Approved by OMB[1]
No. 3150-0183
Expires 08/31/2010

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE

Name of State/Regional Program: California
Reporting Period: May 1, 2004, to March 7, 2008

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State or Region may copy the previous answer, if appropriate.

A. GENERAL

1. Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review.

   See Attachment A

B. COMMON PERFORMANCE INDICATORS

I. Technical Staffing and Training

2. Please provide the following organization charts, including names and positions:

   (a) A chart showing positions from Governor down to Radiation Control Program Director;

   See Attachment B and C

   (b) A chart showing positions of current radiation control program including management; and

   See Attachment D

   (c) Equivalent charts for sealed source and device evaluation, low-level radioactive waste and uranium recovery programs, if applicable.

   There are no current LLRW or uranium recovery programs. The SS&D program is included in the Licensing Section in Attachment D.

3. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) full-time equivalents (FTE) applied to the

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radioactive materials program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, low-level radioactive waste, uranium recovery, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

Name	Position	Area of Effort	FTE%

Please refer back to Attachment D. Note that RHB does not track time spent by technical staff on administrative duties, although this does take a substantial amount of technical staff time.

There is one full-time position in addition to those shown in Attachment D that performs radiological laboratory analyses in support of RHB's materials program. No consultants have been used to perform Agreement State functions.

4. Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, as appropriate.

Returning Staff:

Beverly Hill, Associate HP – November 2004
AA equivalent, HP Technology
17 years, HP Technician Experience
7 years, RHB, Associate HP

Ron Rogus, PhD, Associate HP – August 2005
Ph.D., Medical Physics
5 years, Researcher, MIT
10 years, RHB, Associate HP

Delia Aquino, Associate HP – March 2007
BS, Chemistry
MS, Health Physics
2 years, University of Southern California (USC), RSO
4 years, RHB, Associate HP
11 years, USC, Health Physicist

Fred Toyama, Associate HP – July 2007
Returned as a Retired Annuitant (half-time)
B.S., Biology
40 years, RHB, Associate HP

Jerry Hensley, CHP, Associate HP – December 2007
BS, Applied Science and Technology, Radiation Protection
4 years, Department of the Air Force, Supervisory Health Physicist

3 years, RHB, Associate HP
3 years, PNNL, Senior Research Scientist

New Staff:

Brian Goode, Associate HP – April 2005
B.S., Radiologic Technology
7 years HP experience

Regina Jones, Associate HP – April 2005
B.S., Biological Sciences
No prior experience

Joji Ortego, (LAC), Radiation Specialist – May 2005
B.S., Health Sciences, Radiologic Technology
12 years, LAC, Radiation Specialist, X-Ray

Thomas Pomales, Associate HP – November 2005
Left Program December 2007

Prem Gambhir, Associate HP – January 2006
Ph.D., Agricultural Physics
10 years HP experience

Major League, Junior HP – January 2006
Left Program June 2006

Carol Rexroth, Assistant HP – January 2006
B.S., Biology
No prior experience

Andrew Taylor, Assistant HP – January 2006
BS, Mathematics and Statistics
BS, Environmental Science
6 years, US Navy, Mechanical Operator, Nuclear Mechanic

Jennifer Granger, Associate HP – March 2006
B.S., Environmental Health/Health Physics
6 years, HP at Catawba Nuclear Station and
Rancho Seco Nuclear Generating Station
11 years, HP, UC Davis Medical Center

Ephrime Mekuria, Associate HP – April 2006
B.S., Electrical Engineering
12 years HP experience

Brett Brovan, Associate HP – March 2006
Left program December 14, 2007

Kathleen Harkness, Associate HP – May 2006
BS, Biological Sciences
7 years, University of California, Irvine, EH&S Spec. I, Radiation Safety
5 years, San Onofre Nuclear Generating Station, Senior HP Technician

Paul Lavely, Associate HP – October 2006
B.S., Health Physics
30 years experience, including RSO at UC Berkeley

5. Please list all professional staff who have not yet met the qualification requirements for a license reviewer or materials inspector. For each, list the courses or equivalent training/experience they need and a tentative schedule for completion of these requirements.

Professional staff work under the supervision of a Senior Health Physicist, who oversees their work product. On-the-job training is used extensively to allow reviewers and inspectors to be productive if formal training is delayed. As classes are announced, RHB will be applying to send staff as space is made available to us. RHB remains interested in bringing NRC training to the State of California, since we have such a large professional staff and authorization for out-of-state travel may be an issue irrespective of the funding source.

See Attachment E for a summary of classroom training needs.

6. Identify any changes to your qualification and training procedure that occurred during the review period.

Licensing Section – See Attachment F

ICE Section – See Attachment G

7. Please identify the technical staff that left your program during the review period.

Tara Goode – July 2004 (left agency)

Marcia Smith – December 2004 (retired)

Paul Kovach – January 2005 (left agency)

Delia Aquino – April 2005 (left agency)

Frieda Taylor – May 2005 (reassigned to X-ray program)

Rene O'Bear – August 2005 (retired)

Don Oesterle – September 2004 (transferred to another Branch)

Jan Hillman – December 2005 (reassigned to X-ray program)

Sudana Kwok – November 2005 (reassigned to X-ray program)

C.J. Salgado – January 2006 (reassigned to X-ray program)

Reza Omour – January 2006 (reassigned to X-ray program)

Jeff Clifford – February 2006 (deceased)

Ed Bailey – July 2006 (retired)

Valerie Chenoweth-Brown – June 2006 (reassigned to X-ray program)

Ed Gloor – June 2006 (reassigned to X-ray program)

Major League – June 2006 (left agency)

Victor Anderson – August 2006 (reassigned to ER program)

Stephen Pay – October 2007 (left agency)

Tom Pomales – December 2007 (left agency)

Brett Brovan – December 2007 (left agency)

Franklin Mark – February 2008 (left agency)

Eileen Struthers – SDC (reassigned to X-ray program)

Mark Pietz – (reassigned to X-ray program)

8. List any vacant positions in your program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

Licensing Section Chief
Re-Directed to Branch Chief in April 2006

Licensing Projects Unit
Senior HP - Serving Limited Term Appointment at ICE Section Chief since September 2006
One Associate HP vacancy since March 2008

Radiologic Assessment Unit

One Associate HP vacancy since December 2007

Medical and Academic Licensing Unit
One Associate HP vacancy since December 2007

9. For Agreement States, does your program have an oversight board or committee which provides direction to the program and is composed of licensees and/or members of the public? If so, please describe the procedures used to avoid any potential conflict of interest.

There is a Nuclear Medicine Council, but they have been inactive since prior to the last IMPEP.

II. Status of Materials Inspection Program

10. Please identify individual licensees or categories of licensees the State is inspecting less frequently than called for in NRC's Inspection Manual Chapter (IMC) 2800 and explain the reason for the difference. The list only needs to include the following information: licensee name, license number, your inspection interval, and rationale for the difference.

The only licensees purposely being inspected less frequently than the IMC 2800 schedule are HDRAs, which are inspected on a three-year basis (instead of a two-year basis). This practice was examined in the last two IMPEP reviews without negative comment (and was noted as a "good practice" in 1999 IMPEP).

11. Please provide the number of routine inspections of Priority 1, 2, and 3 licensees, as defined in IMC 2800; the number of initial inspections; and the number of increased controls inspections that were completed during the review period.

Number of Routine Priority 1, 2, & 3 Inspections (7/1/04 -1/31/08):

Priority 1 = 126 Priority 2 = 195 Priority 3 = 482

Note: RHB priorities did not always conform to NRC MC 2800 during the entire IMPEP review period due to the following: 1) RHB did not reprioritize inspections to match the late 2003 NRC reprioritization (reducing most inspection priorities) until early 2005; 2) HDRA licensees are priority 3 (as noted in response to question # 10 above); 3) a few medical licenses were prioritized as priority 5 (instead of priority 3) for a period from 2005 to 2007, and 4) a large number of medical licenses were re-prioritized as priority 3 (instead of priority 5) for a period from 2007 to 2008.

Number of Initial Inspections Completed (7/1/04 – 2/29/07)

Initial Inspections (Priority 1 – 3) = 129
Initial Inspections (Priority 5 – 6) will be provided at the on-site review.

Number of Increased Controls Inspection Completed (7/1/04 – 2/15/07)
Initial IC Inspections = 127 *Routine IC Inspections = 10*

12. Please submit a table, or a computer printout, that identifies inspections of Priority 1, 2, and 3 licensees, increased controls, and initial inspections that were conducted overdue per the applicable guidance. Priority 1, 2, and 3 licensees and initial inspections must be conducted at least as frequently as the inspection intervals established in IMC 2800. Increased controls inspections should be conducted at the intervals established in the Staff Requirements Memorandum for COMSECY-05-0028.

    At a minimum, the list should include the following information for each inspection that was conducted overdue during the review period:

    (1) Licensee Name
    (2) License Number
    (3) Priority (IMC 2800)
    (4) Last inspection date or license issuance date, if initial inspection
    (5) Date Due
    (6) Date Performed
    (7) Amount of Time Overdue
    (8) Date inspection findings issued

    A separate electronic report of all inspections conducted during the IMPEP period is being prepared, which will include all those inspections conducted on an overdue basis. This report will be available during your on-site review.

13. Please submit a table or computer printout that identifies any Priority 1, 2, and 3 licensees, increased controls, and initial inspections that are currently overdue, per the applicable guidance. At a minimum, the list should include the same information for each overdue inspection provided for Question 12 plus your action plan for completing the inspection.

    As of March 31, 2008, no priority 1, 2, or 3 inspections are expected to be overdue.

14. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in IMC 1220 and the number of candidate licensee reciprocity inspections that were completed each year during the review period.

    See Attachment H

III. Technical Quality of Inspections

15. What, if any, changes were made to your written inspection procedures during the reporting period?

We continually update our inspection procedures as may be necessary. A number of such updates were made during this IMPEP review period, mainly pertaining to changes made to correct shortcomings from the previous IMPEP, and as needed to incorporate the IC inspections. Our written inspection procedures will be available for the IMPEP review team.

Also, please refer back to Attachment G

16. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

Inspector	Supervisor	License Category	Date

See Attachment I

17. Describe or provide an update on your instrumentation, methods of calibration and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available throughout the review period?

RHB maintains an ample supply of calibrated survey instruments to support inspectors in the field. Calibrations and repairs of all instruments are provided through a contract with a California licensed calibration service provider (The Medical Physics Center). Each inspector has the following survey instruments/detectors available to them:

- *Energy compensated GM or ion chamber*
- *Pancake GM probe*
- *Low energy NaI (Tl) probe (thin)*
- *High energy NaI(Tl) probe (1x1)*
- *Alpha scintillation probe*
- *Beta scintillation probe (optional)*

In addition to the instruments listed, RHB's inspectors utilize portable MCAs. Since the portable MCAs are only used for qualitative identification, they are not routinely calibrated. All other survey instruments are calibrated annually.

IV. Technical Quality of Licensing Actions

18. How many specific radioactive material licenses does the Program regulate at this time?

Approximately 2030

19. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period.

See Attachments J and K

20. Identify any licensees or groups of licensees that were issued increased controls during the review period. Those licensees that were initially identified during the initial implementation of increased controls need not be listed.

0305 The Aerospace Corporation
0312 El Camino Hospital
0819 Palomar Memorial Center
1078 Permanente Medical Group
1585 Washington Hospital Healthcare
1709 Kaweah Delta District Hospital
2058 Kaiser Permanente Medical Care Program
2072 Permanente Medical Group, Inc.
3693 North Oaks Radiation Center
6831 Tesoro Refining and Marketing Company
7177 American Radiosurgery, Inc.
7500 Nova RX
7525 South Bay Inspection, Inc.
7634 PDL Biopharma, Inc.
7662 Arminius Corporation

21. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

None granted.

22. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

We u*pdated Inspection Priority frequencies in RML 05-001 (changes in **bold**) and developed a new RML training Procedure.*

See Attachments L and refer back to Attachment F

23. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

See Attachment M

Action Plan: The Medical and Academic Licensing Unit has experienced sharp turnover and new employees still are in a training mode. The Licensing Projects

Unit has streamlined their review of the gauge license renewals, and the Industrial Unit has hired a retired annuitant to help reduce the backlog.

V. Technical Quality of Incident and Allegation Activities

24. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See Procedure SA-300, *Reporting Material Events*, for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:

Licensee Name	License #	Date of Incident/Report	Type of Incident

We believe that all reportable events have previously been reported IAW SA-300.

25. During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified? For States, was timely notification made to NRC? For Regions, was an appropriate and timely PN generated? For Agreement States, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.

See Attachment N

26. Identify any changes to your procedures for responding to incidents and allegations that occurred during the period of this review.

We continually update our procedures for responding to incidents and allegations as may be necessary. A number of such updates were made during this IMPEP review period, mainly pertaining to changes made to correct shortcomings from the previous IMPEP. Our written incident/allegation procedures will be available for the IMPEP review team.

Also, please refer back to Attachment G

C. NON-COMMON PERFORMANCE INDICATORS

I. Compatibility Requirements

27. Please list all currently effective legislation that affects the radiation control program. Denote any legislation that was enacted or amended during the review period.

a) Radiation Control Law (Health & Saf. Code, §§114960 et seq.)

b) Radiation Protection Act of 1993 (Health & Saf. Code, §§114650 et seq.)

c) Containment of Radioactive Materials (Health & Saf. Code, §§114705 et seq.)

d) No legislation relating to activities subject to IMPEP was enacted or amended during the review period.

28. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

The Radiation Control Regulations are not subject to a "Sunset" or equivalent law.

29. Please review and verify that the information in the enclosed State Regulation Status (SRS) sheet is correct. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them. If legally binding requirements were used in lieu of regulations, please describe their use.

See Attachments O and P

30. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

1. Regulatory Process Map – See Attachment Q

2. Regulatory Process Detailed Notes – See Attachments R and S

3. Regulatory Process Timelines for Non-Emergency and Emergency regulations – See Attachments T and U

4. How to Participate in the Rulemaking Process – See Attachment V

The following is a list of other state laws that must also be considered during regulation promulgation:

- *Public Records Act*
- *Information Practices Act*
- *Bagley-Keen Open Meeting Act*
- *State Records Management Act*
- *Government Code, §§17500-17613*
- *State Building Standards Law*
- *Suspension of statutes, rules and regulations during state of emergency*

A copy of the above identified regulations and laws are available for review.

II. Sealed Source and Device (SS&D) Evaluation Program

31. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of devices issued during the review period. The table heading should be:

SS&D Registry Number	Manufacturer, Distributor or Custom User	Product Type or Use	Date Issued	Type of Action

See Attachment W

32. Please include information on the following questions in Section A, as they apply to the SS&D Program:

Technical Staffing and Training - Questions 2-9
Technical Quality of Licensing Actions - Questions 18-23
Technical Quality of Incident and Allegation Activities - Questions 24-26

Responses to these earlier questions include information related to the SS&D Program, which is part of the Licensing Project Unit.

III. Low-Level Radioactive Waste Disposal Program

33. Please include information on the following questions in Section A, as they apply to the Low-Level Radioactive Waste Disposal Program:

Technical Staffing and Training - Questions 2-9
Status of Materials Inspection Program - Questions 10-14
Technical Quality of Inspections - Questions 15-17
Technical Quality of Licensing Actions - Questions 18-23
Technical Quality of Incident and Allegation Activities - Questions 24-26

Not applicable

IV. Uranium Recovery Program

34. Please include information on the following questions in Section A, as they apply to the Uranium Recovery Program:

Technical Staffing and Training - Questions 2-9
Status of Materials Inspection Program - Questions 10-14
Technical Quality of Inspections - Questions 15-17
Technical Quality of Licensing Actions - Questions 18-23
Technical Quality of Incident and Allegation Activities - Questions 24-26

Not applicable

ATTACHMENT A

Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review.

Recommendation 1:
The review team recommends that the State ensure that adequate resources, both funding and staffing, be devoted to the radiation control program.

In June 2005, regulations became effective increasing the initial and annual fees that RHB charged for California Radioactive Materials Licenses and X-ray machine registrations . In addition, the Governor's budget authorized the expenditure of monies generated by these new fees. This allowed RHB to recruit and hire nine new radioactive materials health physicists during 2006. Nevertheless, due to 1) a reorganization of RHB during 2006 (which required additional resources in the X-ray sections), 2) retirements, and 3) salaries lagging behind other State agencies hiring scientists, between 2004 – 2008, there was a net loss of five health physicists from the radioactive materials program. RHB continues to work on solutions to the recruitment and retention problems we face.

Recommendation 5:
The review team recommends that the Branch, in coordination with INEEL, complete and close all reportable incidents in NMED.

At the time of the previous IMPEP review, there were approximately 200 open California NMED events. As of March 1, 2008, only one of these events remained open, and it may be closed by the time of the onsite IMPEP review. In addition to the one event from the previous IMPEP review period, there were seven NMED events that had been open more that six months, out of a total of over 500 NMED reports that were submitted by California during the current IMPEP review period.

Recommendation 7:
The review team recommends that the Branch establish and implement a system to track incident and allegation investigations to ensure timeliness, proper documentation, appropriate follow up, and closure.

Such a system has been implemented.

Recommendation 8:
The review team recommends that the Branch develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 4.1.2 of the 2004 IMPEP report).

The Branch must work within the constraints of California statutes to promulgate regulation. California statutes and administrative procedures provide for numerous checks and balances that require the involvement of State agencies that are outside of the control of the Branch. This recommendation has been followed closely during the heightened oversight calls, and the IMPEP team should refer to the minutes of those calls for the status.

The following recommendations were closed after the 2006 follow-up IMPEP:

Recommendations 2, 3, 4, 6, 9, and 10. See Items 2 and 5, MRB Minutes, June 15, 2006.

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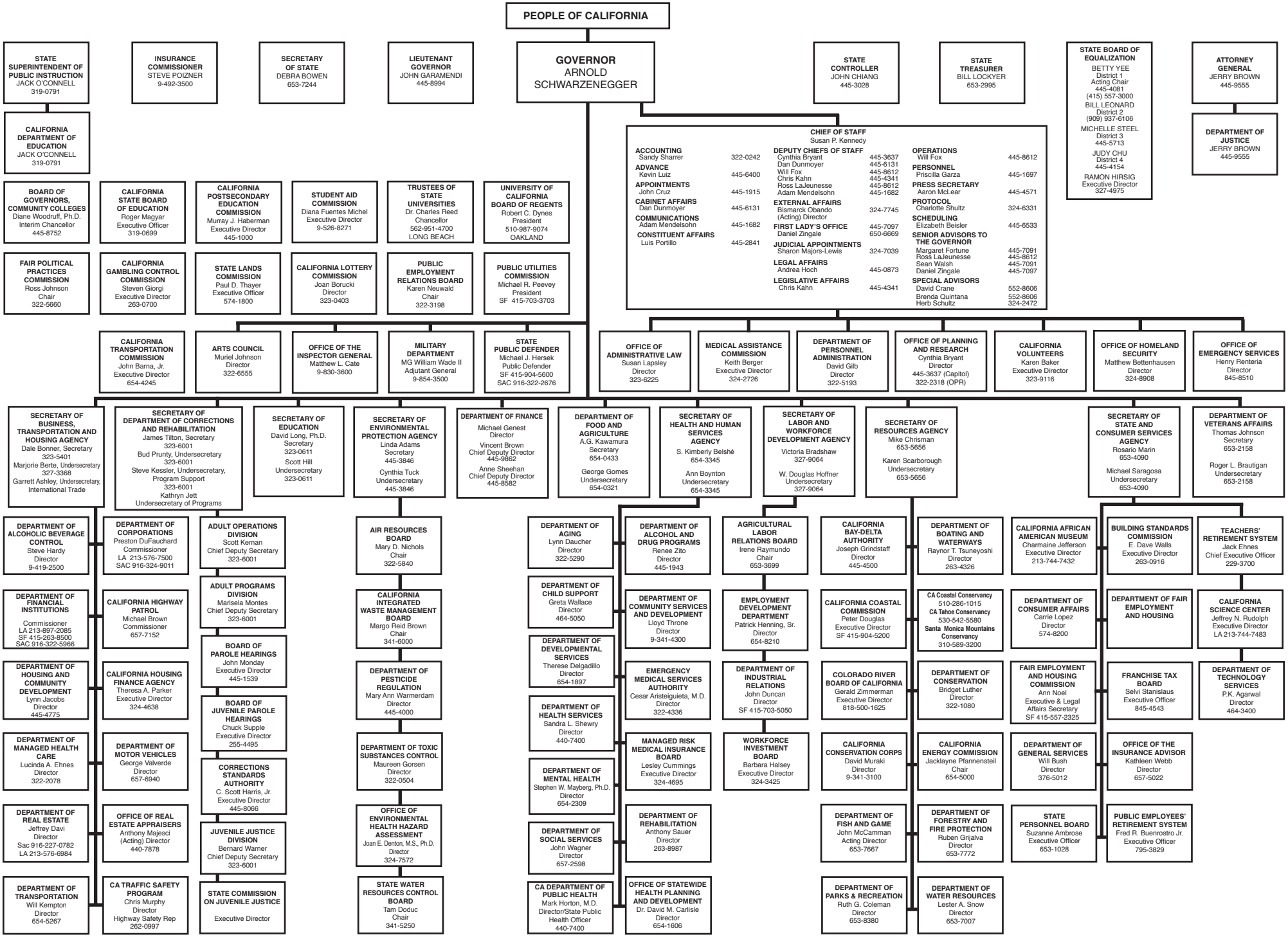


California Department of Public Health

California Conference of
Local Health Officers
Roberta Lawson

Department of Public Health
Director/State Public Health Officer
Mark B Horton, MD, MSPH

Special Assistant to the Director
Jean Iacino

Office of Civil Rights
Ernesto Cordova (Acting)

Chief Deputy Director of Operations
Mary Winkley

Chief Deputy Director of Policy & Programs
Bonita Sorensen, MD, MBA

Associate Director
External Affairs
Janet Huston

Administration
Richard J. Rodriguez

Office of Legal Services
Kathleen Keeshen

Information Technology Services
Bob Ferguson

Internal Audits
David Mansoor

Office of the State Laboratory Director
Paul Kimsey, Ph.D

Coordinating Office
For Obesity Prevention
Lisa Hershey (Acting)

Health Information & Strategic Planning
Linette Scott, MD

Public Health Emergency Preparedness
Betsey H. Lyman

Office of Public Affairs
Suanne Buggy

Public Health Advisory Committee

Office of Legislative & Governmental Affairs
Monica Wagoner

Office of Multicultural Health
Vacant

Office of Binational Border Health
John Kurata (Acting)

Office of Women's Health
Terri Thorfinnson

Center for Chronic Disease Prevention & Health Promotion
Donald Lyman, MD (Acting)

Center for Infectious Disease
Gil Chavez, MD

Center for Family Health
Catherine Camacho

Center for Environmental Health
Rufus Howell (Acting)

Center for Healthcare Quality
Kathleen Billingsley

Chronic Disease & Injury Control
Donald Lyman, MD

Environmental & Occupational Disease Control

Office of AIDS
Michelle Roland, MD

Communicable Disease Control
Douglas Hatch, MD

Women, Infants, & Children
Linnea Sallack

Maternal, Child, & Adolescent Health
Shabbir Ahmad (Acting)

Office of Family Planning
Laurie Weaver

Genetic Disease
Fred Lorey (Acting)

Food, Drug, & Radiation Safety
Vacant

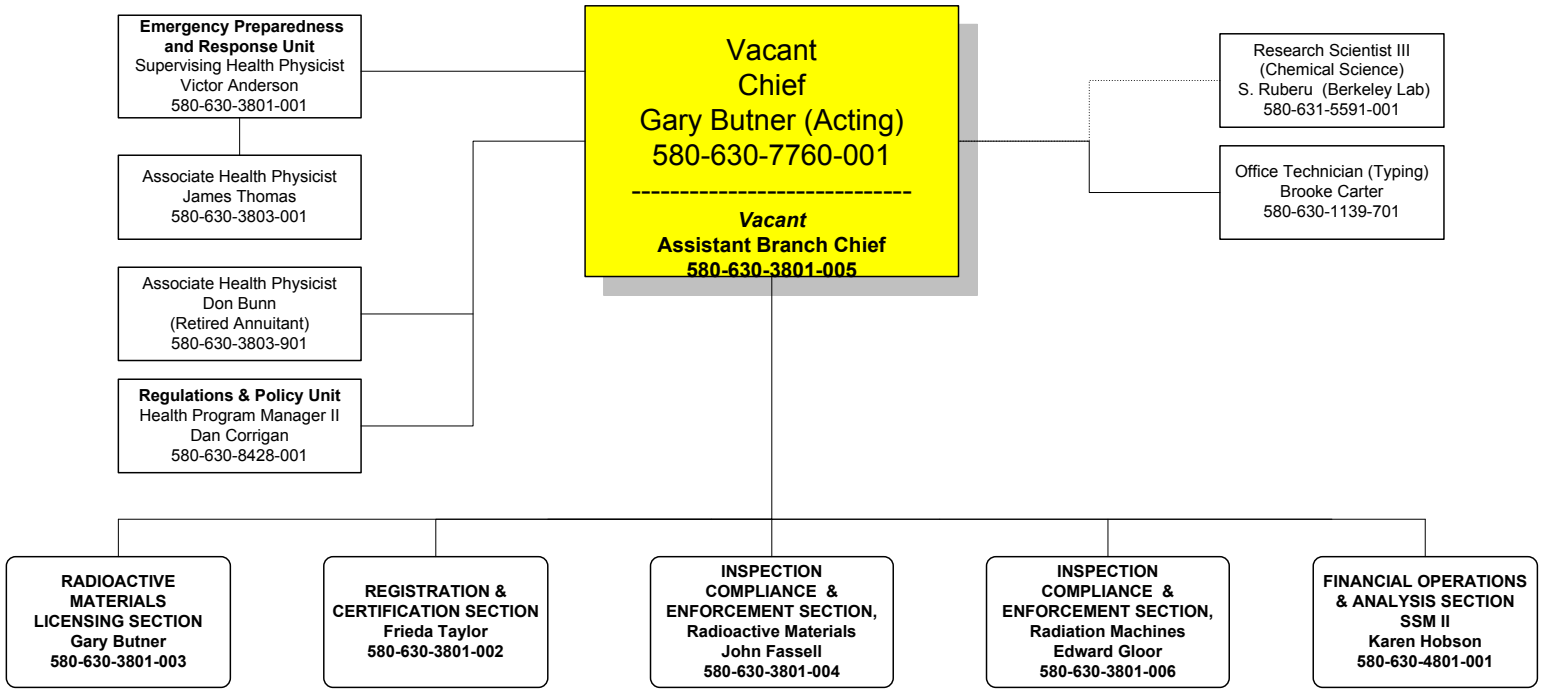
Drinking Water & Environmental Management
Rufus Howell

Licensing & Certification
Kathleen Billingsley

Laboratory Field Services
Dr. Karen Nickels

February 27, 2008

Radiologic Health Branch
Division of Food, Drug, and Radiation Safety



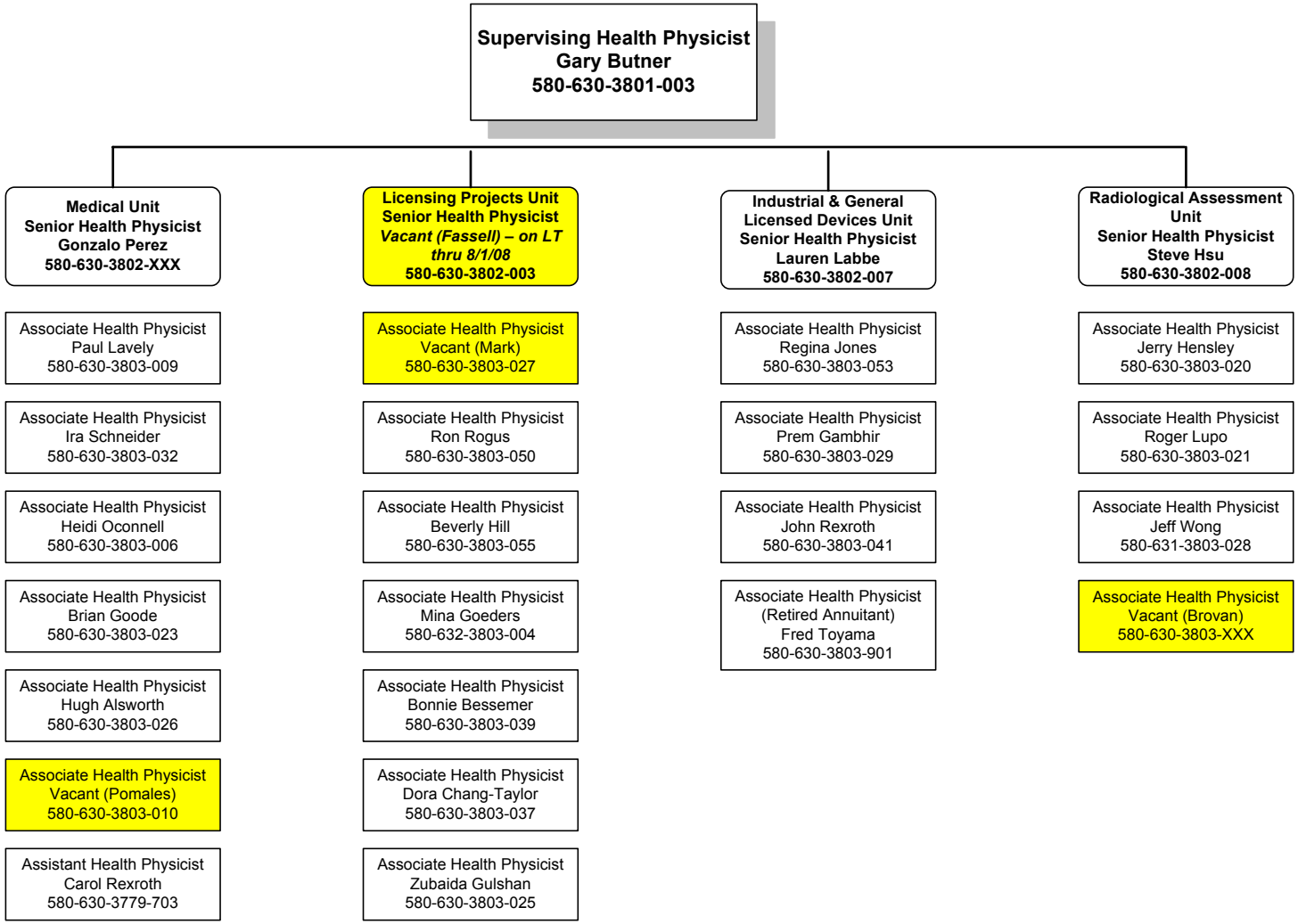
Approved:

Gary Butner, Acting Branch Chief

Drew Johnson, Acting Division Chief, Food, Drug & Radiation Safety

02/26/08

Radioactive Materials Licensing Section



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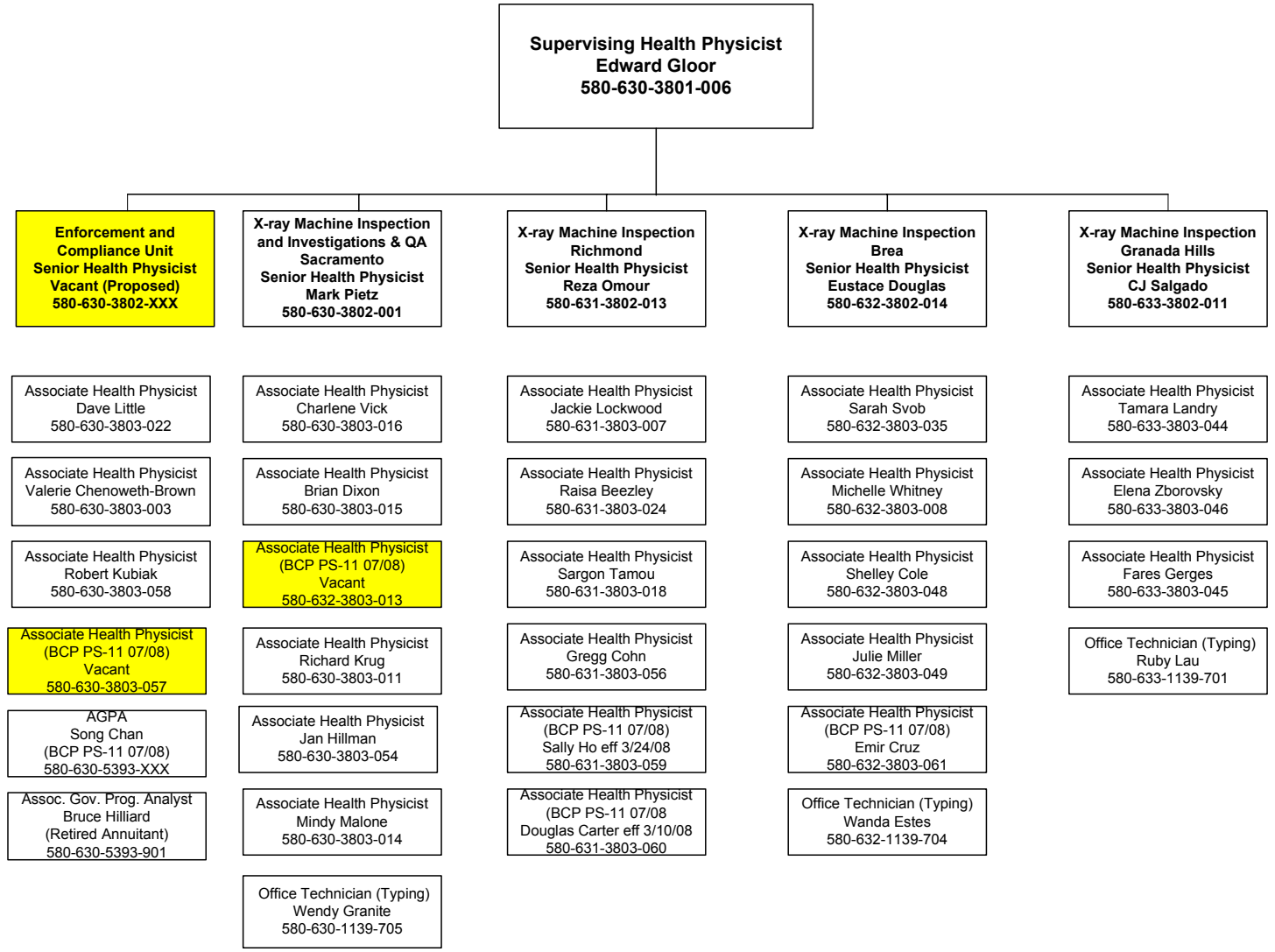
Inspection, Compliance and Enforcement Section, Radiation Machines



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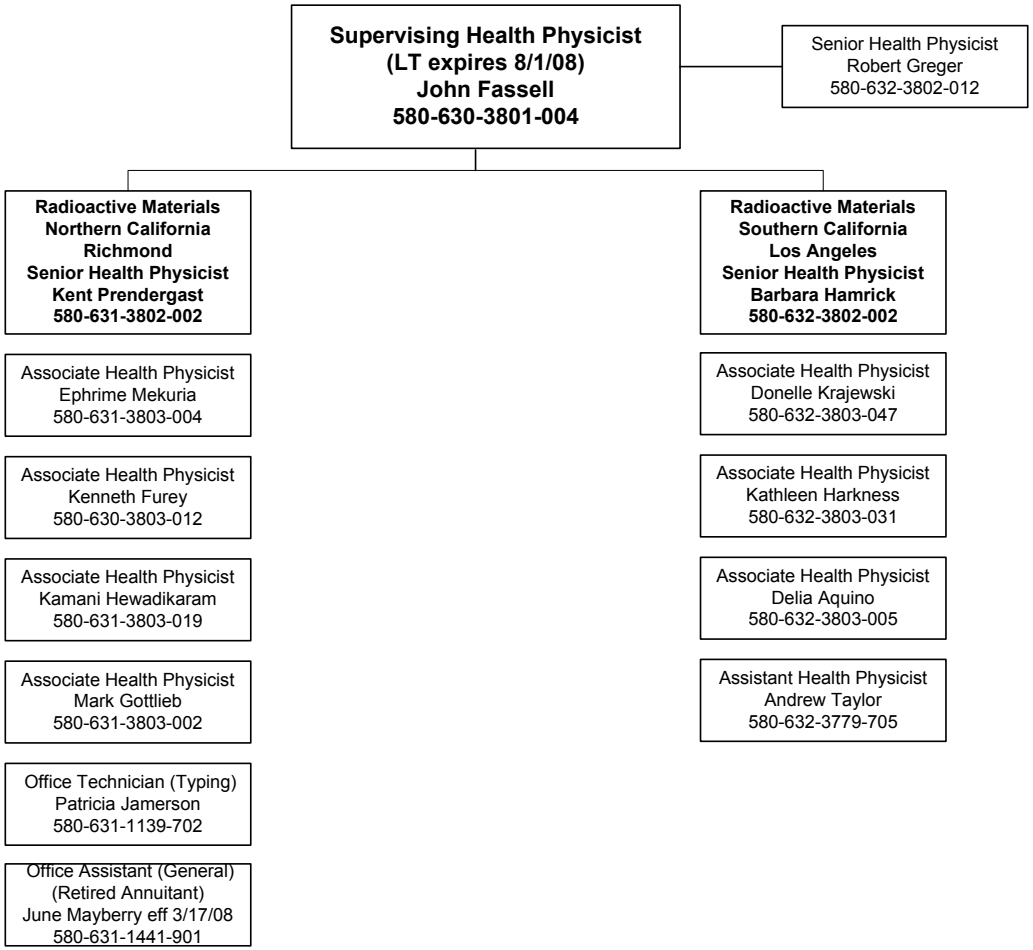
Inspection, Compliance and Enforcement Section, Radioactive Materials



Regulations Unit

Health Program Manager II
Dan Corrigan
580-630-8428-001

Senior Health Physicist
Phillip Scott
580-630-3802-006

Associate Health Physicist
Leo Spencer
580-630-3803-051

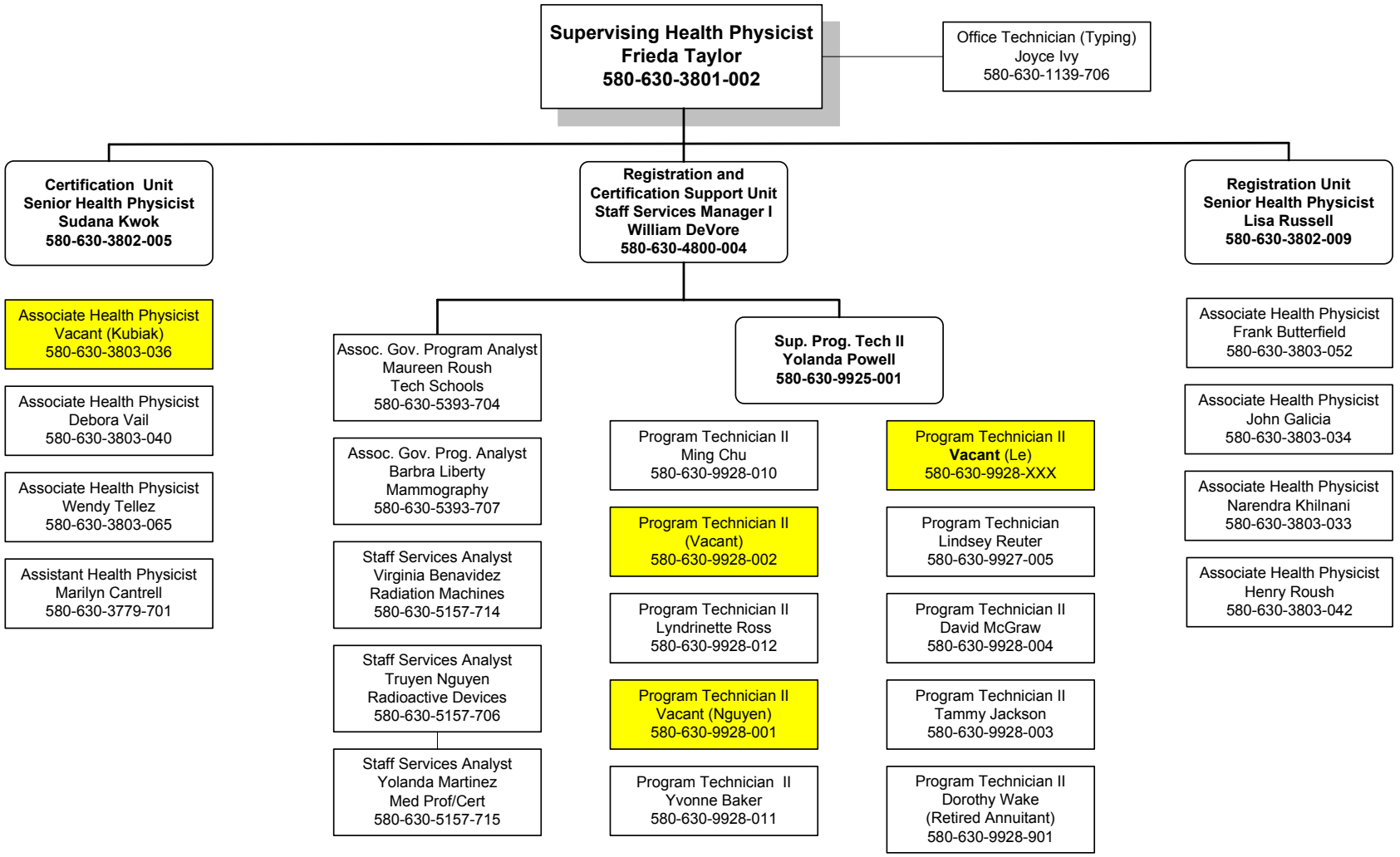
Associate Health Physicist
Jennifer Granger
580-630-3803-017

Assoc. Gov. Program Analyst
Judy Hardy
580-630-5393-711

Associate Health Physicist
William Lorenzo
(Retired Annuitant)
580-630-3803-901

Assistant Health Physicist
(BCP PS-11 07/08)
Vacant
580-630-3779-XXX

Registration and Certification Section



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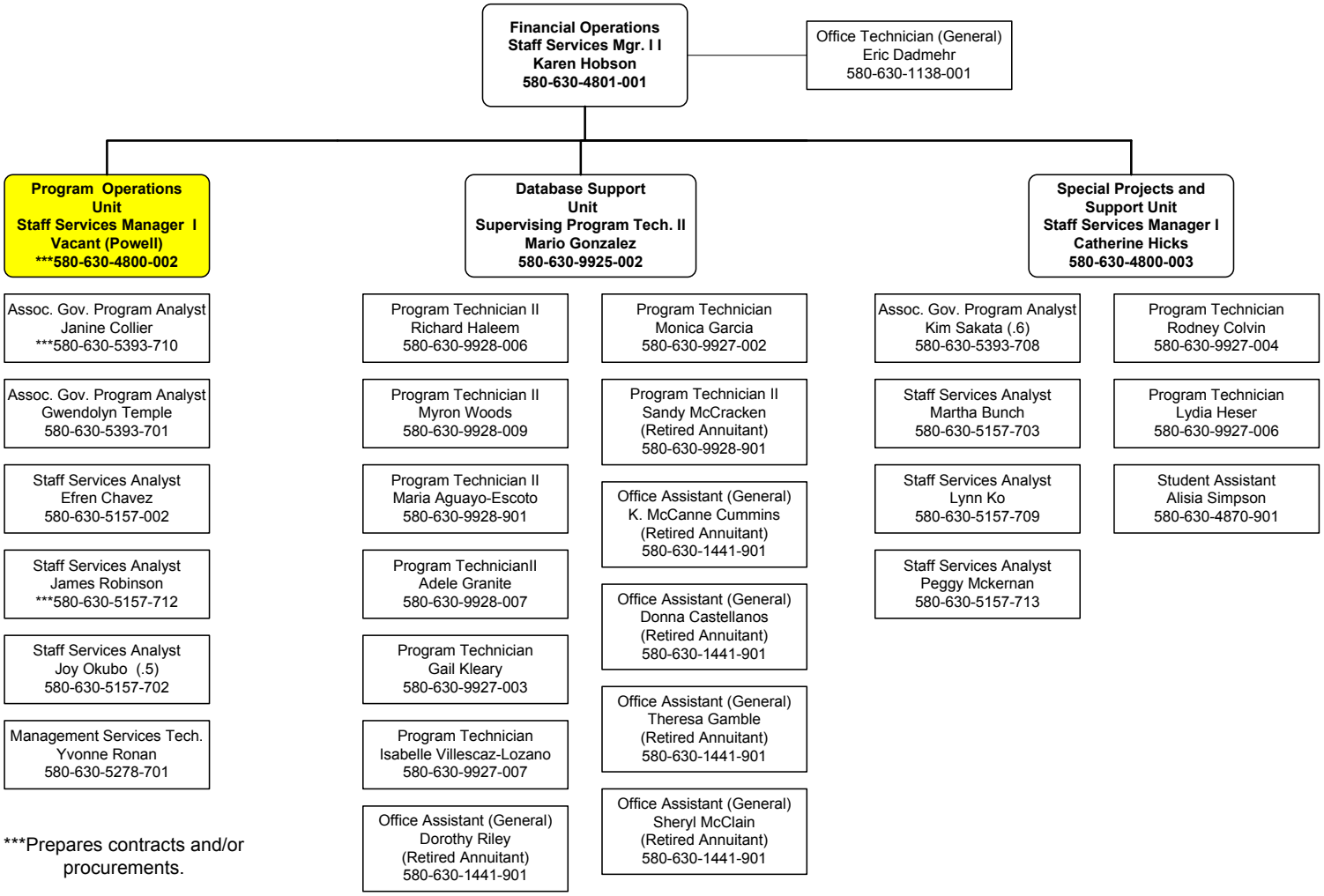
Financial Operations and Analysis Section



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	DOT	IR	WL	NM	Th	ID	HW	AS	EM	MARLAP	IT	SS&D	D&D	IP	LP
Licensing Section															
Industrial Unit															
Prem Ghambhir	Mar-08	X				X									
Regina Jones	Mar-08	X				X									
John Rexroth						X									
Lauren Labbe, Senior						X	X	X	X	X					
Licensing Projects Unit															
Zubaida Gulshan						X	X	X	X	X	X		X	X	
D. Taylor						X	X	X	X	X	X		X	X	
Beverly Hill	X					X					X	X			
Ron Rogus						X		X			X				
Bonnie Bessemer						X					X				
John Fassell, Senior						X	X	X	X	X	X		X		
Medical and Academic Unit															
Ira Schneider					X	X	X	X	X	X			X	X	
Hugh Alsworth						X	X	X	X	X			X	X	
Brian Goode	X				X	X									
Paul Lavely	X			X	X	X		X	X	X			X	X	Mar-08
Carol Rexroth	X			X	X	X									
Heidi O'Connell	X				X	X									
Gonzalo Perez, Senior						X		X		X			X		
X = Needs course to be fully qualified															
ICE Section															
RM - North															
Ephrime Mekuria	X	Mar-08		X	X										
RM - South															
Andrew Taylor			X	Mar-08	Aug-08						X				
Kathleen Harkness		Mar-08			Aug-08						X				
LA County															
Josephine Ortego				X	X										
DOT = Transportation															
WL = Well Logging															
IR = Industrial Radiography															
NM = Nuclear Medicine															
Th = Therapy															
ID = Internal Dosimetry															
HW = HAZWOPER															
AS = Air Sampling															
EM = Environmental Monitoring															
IT = Irradiator Technology															
IP = Inspection Procedures															
LP = Licensing Procedures															

ATTACHMENT F

Procedure Number: **07-01**
Effective Date: June 1, 2007
Supersedes: none
Prepared By: Gonzalo Perez
Reviewed By: Franklin Mark
Approved By: Gary Butner

Procedure Title: **Training Program for Radioactive Materials Licensing Health Physicists**

1.0 PURPOSE:

The purpose of this procedure is to provide guidance and instruction to Radioactive Materials Licensing (RML) personnel in the implementation of a training program for health physicists who perform radioactive material licensing.

2.0 APPLICABILITY AND SCOPE:

2.1 This procedure applies to all health physicists assigned to the RML Section.

2.2 The scope of this procedure is to provide training to health physicists that is relevant to their assignments in the RML Section. All staff health physicists are expected to meet the quality standards expressed within the NRC documents referenced in section 3.0 of this procedure.

3.0 REFERENCES:

3.1 NRC Inspection Manual Chapter 1246, FORMAL QUALIFICATION PROGRAMS IN THE NUCLEAR MATERIAL SAFETY AND SAFEGUARDS PROGRAM AREA.

3.2 SP 97-087, NRC/OAS TRAINING WORKING GROUP, RECOMMENDATIONS FOR AGREEMENT STATE TRAINING PROGRAMS.

3.3 NRC Inspection Manual, Appendix 1246 AO9, Section IX: TRAINING REQUIREMENTS FOR DECOMMISSIONING INSPECTORS.

3.4 NRC Inspection Manual, Appendix 1246 A10, Section X: TRAINING REQUIREMENTS FOR DECOMMISSIONING PROJECT MANAGERS/TECHNICAL REVIEWERS.

3.5 NRC Inspection Manual, Appendix 1246 A11, Section XI: TRAINING REQUIREMENTS FOR MATERIALS EXEMPT DISTRIBUTION LICENSE REVIEWER.

3.6 NRC Inspection Manual, Chapter 1246 A17, Section XVII: TECHNICAL REVIEWER QUALIFICATIONS JOURNAL BYPRODUCT MATERIAL SEALED SOURCE AND DEVICE REVIEWERS.

4.0 DEFINITIONS:

None.

5.0 RESPONSIBILITIES:

5.1 Radiologic Health Branch Chief

The Branch Chief is responsible for assuring that adequate support and resources are available for training.

5.2 RML Supervising Health Physicist

The RML Supervising Health Physicist is responsible for assuring that the unit seniors implement this procedure. The RML Supervising Health Physicist coordinates the training activities of the RML section with the Branch.

5.3 Unit Senior Health Physicist

Unit Senior Health Physicists monitor the training of Health Physicists assigned to their units. Unit seniors assure that each member attends required training and documents that training. The Unit seniors prepare an annual training plan for each health physicist assigned to their units. The unit senior ensures that the health physicist maintains a copy or record of that training.

5.4 Individual Health Physicists(Junior, Assistant, Senior, Supervisor HP)

All Health Physicists are responsible for attending assigned training and documenting that training. Documentation consists of the maintenance of the individual training journal (See Attachment 1) and providing copies of training certificates or records and dates of completion of course work to the Technical Training Coordinator.

5.5 Technical Training Coordinator

The Technical Training Coordinator is the Office Technician assigned to the RHB Branch Chief or in that person's absence another Office Technician appointed by the Branch Chief. The Technical Training Coordinator:

5.5.1 Keeps copies of all certificates of completion for training

5.5.2 Maintains a master data base of all technical training completed by health physicists assigned to the Branch as well as past members of the Branch.

5.5.3 Assists health physicists with the completion of training request forms (STD 697).

5.5.4 When necessary, coordinates travel requests and registration for NRC classes.

5.5.5 Maintains a "tickler" file of which health physicists are scheduled to attend training or have attended training to assure that certificates of completion are transmitted to the Technical Training Coordinator.

6.0 COMMUNICATION/DOCUMENTATION:

6.1 Training is documented by:

6.1.1 Certificates of completion from the training organization.

6.1.2 Completion of the individual training journal (Attachment 1.)

6.1.3 Annotation of training completion dates on the master training file or data base.

6.2 Training requests for all training are made on the Training Registration form, STD 697.

6.3 Out-of-state travel is requested on the Out-of-State Travel request form, STD 257 or STD 257C.

6.4 Requests for NRC sponsored training courses are made using Application Training Course/Workshop Form (Enclosure 2 of the NRC Training course listing for the current Federal fiscal year). The HP's complete the form and submit to the RHB technical training coordinator. The NRC may also require that requests for NRC sponsored training be made on a special form for a specific training course.

7.0 FACILITIES, EQUIPMENT, SUPPLIES:

Facilities, equipment, and supplies will be determined by the individual training course. Normally, these items will be supplied by the organization delivering the training.

8.0 PROCEDURE:

8.1 It is the goal of the RML Section Chief to have each new Health Physicist working in the RML section fully trained within 24 months of being hired. Fully trained means being qualified in each of the areas listed below in sections 8.2, 8.3, and 8.4. Health Physicists who are currently assigned to the RML Section will have a goal of becoming fully qualified within 24 months of the date this procedure becomes effective.

8.2 Basic Health Physics Knowledge Requirements

8.2.1 Individuals who possess a bachelor of science degree or higher in health physics or are certified by the American Board of Health Physics (C.H.P.) have met the basic health physics knowledge requirements.

8.2.2 Individuals with five or more years of experience in the field of health physics and who do not meet the criteria of section 8.2.1 above shall be evaluated to determine if they meet the basic health physics knowledge requirements.

8.2.2.1 The areas of knowledge are listed in Attachment 2 of this procedure.

8.2.2.2 The evaluation must be done at the supervising health physicist level or higher. The evaluation is documented using Attachment 3.

8.2.2.3 The evaluation may consist of a review of the individual's resume, publications, samples of work and so forth. Individuals may demonstrate competency by passing a test which is approved by the supervising health physicist conducting the review. The test must be equivalent or better in terms of rigor and scope to the final test for the Basic Radiation Protection Technology Course administered by Dr. Daniel Gollnick.

8.2.2.4 Individuals in this category who do not meet the basic competency requirements as outlined above shall take the course work in section 8.2.3 below.

8.2.3 Individuals with less than five years of experience in the health physics field who do not meet the criteria of section 8.2.1 above must attend training which consists of the subject areas in Attachment 2 of this procedure. Competency is demonstrated by achieving a test score of 70% on a scale of zero to 100% for the course given. The following course work or its equivalent must be taken.

8.2.3.1 Completion of the Basic Radiation Protection Technology Course administered by Dr. Daniel Gollnick

AND ONE OR BOTH OF THE FOLLOWING:

8.2.3.2 Completion of NRC Courses H-117, Introductory Health Physics, H-109, 5 Week Basic Health Physics and H-122, Basic Health Physics.

OR

8.2.3.3 Completion of the Applied Health Physics (2 week course)

8.3 Core Specialty Courses

8.3.1 Radioactive Materials License (RML) reviewers must take NRC Course G-109, Licensing Practices and Procedures or its equivalent.

8.3.2 Health physicists in the radioactive materials program must take the following core specialty courses or their equivalents:

8.3.2.1 H-304, Diagnostic & Therapeutic Nuclear Medicine.(M)

8.3.2.2 H-308, Transportation of Radioactive Materials. (All)

8.3.2.3 H-305, Safety Aspects of Industrial Radiography. (I)

8.3.2.4 H-314, Safety Aspects of Well Logging. (I)

8.3.2.5 H-315, Irradiator Technology. (P)

8.3.2.6 H-313, Teletherapy & Brachytherapy. (M)

8.3.2.7 H-312, Internal Dosimetry. (All)

8.3.2.8 NRC Sealed Source and Device Workshop (P)

8.3.3 Qualification to work on large scale decommissioning projects shall be satisfied by completing the following NRC course work or its equivalent.

8.3.3.1 H-111, Environmental Monitoring for Radioactivity

8.3.3.2 H-119, Air Sampling for Radioactive Materials

8.3.3.3 H-120, Decommissioning of Radioactive Materials Facilities.

8.3.3.4 H-121, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM).

8.3.3.5 RESRAD and RESRAD BUILD Programs

8.3.3.6 MARLAP

8.3.3.7 G-108, NRC Inspection Procedures

8.3.3.8 40 Hour HAZWOPPER Training

8.4 Course Equivalency

8.4.1 Course equivalency is demonstrated by taking alternative training which provides coverage equivalent to the areas of training in the NRC lesson plan for the course in question or meets the training standards in reference 3.2.

8.4.2 Alternate training may be accomplished by:

8.4.2.1 Attending a non-NRC sponsored course which provides equivalent training.

8.4.2.2 Completing “on-the-job” (OJT) training.

8.4.2.3 Evaluation of the individual’s training and experience which demonstrates competency in the course area.

8.5 Non-NRC Sponsored Course Work

8.5.1 Non-NRC sponsored courses shall be evaluated to determine that the course content provides equivalent training in the subject matter covered by a NRC sponsored course. This training course evaluation will be assigned by the RML supervising health physicist and will be subsequently approved or disapproved during the evaluation. See Attachment 4 for the course evaluation form.

8.5.2 On the job training (OJT) shall have a training plan in accordance with Attachment 6. OJT shall consist of selected readings, directly supervised activities, and generally supervised activities. The completion of OJT course will be documented on the individuals training journal as well as filed with the technical training coordinator.

8.5.3 A person completing an OJT program will be assigned a trainer. The trainer shall be someone competent in the area being trained. The trainer will normally be the individual’s immediate supervisor. However, the trainer may be another individual in the radioactive materials program.

8.5.4. Evaluation of individual’s experience and training to qualify that person in a specialty area of training is performed using the form in Attachment 3. The evaluation shall consist of a review of the individual’s resume, past training, publications, presentations, and if necessary a more detailed statement of the individual’s duties and responsibilities for assignments in the area under evaluation. The trainer has the option to nullify certain aspects of the OJT Attachment 3 if the employee has already satisfied that portion through other means. Evaluations are normally performed by the

individual's immediate supervisor using the Attachment 5.. The evaluation shall be reviewed and approved by a RML supervising health physicist.

8.6 Supplemental Training

8.6.1 Supplemental training consist of training activities designed to enhance the health physicist's skills, knowledge, and abilities. They add value to the radioactive materials program and contribute to professional development. This training should be documented on the individuals training journal. The following is a partial list of types of supplemental training activities:

8.6.1.1 Health physics courses given by commercial organizations or professional societies.

8.6.1.2 Seminars.

8.6.1.3 Meetings of the Health Physics Society, Council of Radiation Control Program Directors, Organization of Agreement States, and other professional organizations whose activities are mainly concerned with health physics or one of its allied scientific fields.

8.6.1.4 Formal classroom instruction by members of the Branch.

8.7 Radiological Emergency Response Training

8.7.1 Individuals who are assigned to duties involving either Nuclear Emergency Response Program (NERP) or are a member of a California Radiological Emergency Response Team (CREST) shall receive the additional training outlined and defined by the training requirements of those programs. This training should be documented on the individuals training journal.

9.0 ATTACHMENTS:

1 Training Journal
2 Knowledge Areas for Competency
3 Core Competency Evaluation
4 Non-NRC Sponsored Course Evaluation
5 Evaluation of Experience for Core Specialty Certification
6 OJT Documentation

Attachment 1 - Training Journal

9.1

Name: _____

Education: _____

_____

_____

Basic Health Physics Competency Evaluations/Course Work

Degree in Health Physics: Y/N _____

ABHP Certification (C.H.P.): Y/N _____

Evaluation of Competency in Basic Health Physics: Evaluator _____

Equivalency Testing: Date: _____

Test Score: _____

Basic Radiation Protection Technology Course: Date Completed _____

Test Score: _____

NRC Course, H-117, Introductory Health Physics: Date Completed _____

NRC Course, H-122, Basic Health Physics: Date Completed _____

Applied Health Physics (2 week course)

Date Completed _____

Core Specialty Courses

NRC Course G-109, Licensing Practices and Procedures

Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

Attachment 1 Training Journal

NRC Course H-304, Diagnostic & Therapeutic Nuclear Medicine
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

NRC Course H-308, Transportation of Radioactive Materials
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

NRC Course H-305, Safety Aspects of Industrial Radiography
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

NRC Course H-314, Safety Aspects of Well Logging
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

NRC Course H-315, Irradiator Technology
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

Attachment 1 Training Journal

NRC Course H-313, Teletherapy & Brachytherapy
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

NRC Course H-312, Internal Dosimetry
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

NRC Course for Sealed Source and Device Evaluations
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

NRC Course G-205, Root Cause/Incident Investigation Workshop
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

Large Decommissioning Project Specialty Courses

NRC Course H-111, Environmental Monitoring for Radioactivity
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

NRC Course H-119, Air Sampling for Radioactive Materials
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

Attachment 1 Training Journal

NRC Course H-120, Decommissioning of Radioactive Materials Facilities
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

NRC Course H-121, MARSSIM
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

NRC Course on RESRAD and RESRAD BUILD Programs
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

NRC Course on MARLAP
Date Completed _____

Alternative Training Date Completed _____

Course Title: _____

Emergency Response Training – Common Training

Forty Hours Hazardous Waste Operations Training
Date Completed _____

Radiological Emergency Responder Operations (RERO)
Date Completed _____

CREST Unit Training

Incident Command System (ICS) and the State Emergency Management System (SEMS)
Date Completed _____

The National Incident Management System (NIMS)
Date Completed _____

Radiological Dispersal Devices (Characteristics, Potential Uses, And Expected Effects; 20 Hours)

Date Completed _____

Dose Management, Dose Evaluation, And Downwind Dose Assessment For Emergency Operations (20 hours)

Date Completed _____

Conduct And Planning Of Health Physics Operations In Support Of Emergency Responders (20 Hours)

Date Completed _____

Nuclear Emergency Response Program (NERP) Team Training

Emergency Operations Overview (CDHS specific) (once every two years)

Date Completed _____

RASCAL Training (NRC) (once every two years)

Date Completed _____

Emergency Planning Institute REP Course.

Date Completed _____

Emergency Planning Institute Radiological Accident Assessment Course

Date Completed _____

FRMAC Training

Date Completed _____

RAP Team Training

Date Completed _____

Power Plant Systems Class

Date Completed _____

ICS-100/ICS-200

Date Completed _____

Supplemental Training
(Add Pages as Necessary)

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Supplemental Training Continued:
(Add Pages as Necessary)

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Date Completed _____

Training Activity _____

Attachment 2

9.2 Knowledge Areas to Demonstrate Competency in Basic Health Physics.

9.2.1 These knowledge areas are derived from reference 3.2.

9.2.2 Introductory Knowledge (the font appears to have changed below from Arial to Times New Roman)

9.2.2.1 Atomic/Nuclear Structure

9.2.2.2 Modes/Rates of Decay

9.2.2.2.1 Alpha, Beta, Gamma, X-Rays, Neutron

9.2.2.3 Half-Life

9.2.2.3.1 Transient/Secular Equilibrium

9.2.2.4 Production of X-Rays

9.2.2.5 Interaction with Matter

9.2.2.5.1 Photoelectric Effect

9.2.2.5.2 Compton Scattering

9.2.2.5.3 Pair Production

9.2.2.5.4 Neutron Capture

9.2.2.6 Terminology (SI & Special Units)

9.2.2.6.1 Activity

9.2.2.6.2 Dose

9.2.2.6.3 Exposure

9.2.2.7 Background Radiation

9.2.2.8 Exposure Pathways

9.2.2.8.1 Ingestion

Attachment 2

9.2.2.8.2 Inhalation

9.2.2.8.3 Absorption

9.2.2.8.4 Contaminated Wound

9.2.2.8.5 Direct Exposure

9.2.2.9 Biology/Effects of Radiation [2]

9.2.3.9.1 Somatic/Genetic/In-Utero

9.2.2.9.2 Stochastic/Non-Stochastic (Deterministic/Non-Deterministic)

9.2.2.9.3 High Dose Effects

9.2.2.10 Regulatory Environment [2]

9.2.2.10.1 Federal (NRC/DOT/EPA/FDA/OSHA)

9.2.2.10.2 State (Agreement/Non Agreement/CRCPD)

9.2.2.10.3 Advisory Organizations (NCRP/ICRP/IAEA)

9.2.3 APPLICATIONS

9.2.3.1 Sources of Radiation

9.2.3.1.1 Sealed

9.2.3.1.2 Unsealed

9.2.3.13 Plated

9.2.3.1.4 Machine generated

9.2.3.2 Uses

9.2.3.2.1 Medical

9.2.3.2.2 Industrial

9.2.3.2.3 Academic

9.2.3.2.4 Consumer Products

9.2.3.2.5 Reactor/Fuel Cycle

Attachment 2

9.2.3.3 Licensee/Registrant Radiation Safety Program

9.2.3.3.1 Facility Design & Engineering Controls

9.2.3.3.2 ALARA

9.2.3.3.3 Surveys

9.2.3.3.4 Contamination Control/Spills

9.2.3.3.5 Respiratory Protection

9.2.3.3.6 Waste Handling And Disposal

9.2.3.3.7 Dose Assessment

9.2.3.3.8 Transportation

9.2.4 Instruments

9.2.4.1 Detectors (Types And Modes Of Operation)

9.2.4.1.1 Gas Filled

9.2.4.1.1.1 GM

9.2.4.1.1.2 Proportional

9.2.4.1.1.3 Ionization

9.2.4.1.2 Scintillation

9.2.4.1.3 Semiconductor

9.2.4.2 Measurement Systems

9.2.4.2.1 Meters

9.2.4.2.2 Scalers

9.2.4.2.3 Multi Channel Analyzer (MCA)

9.2.4.3 Operational Parameters

9.2.4.3.1 Efficiency

Attachment 2

9.2.4.3.2 Resolution

9.2.4.4 Air Samplers

9.2.4.5 Calibration

9.2.5 Surveys/Monitoring/Statistics

9.2.5.1 Types

9.2.5.1.1 Radiation Levels

9.2.5.1.2 Contamination
9.2.5.1.3 Bioassay

9.2.5.1.4 Effluents

9.2.5.2 Techniques

9.2.5.2.1 Sample Collection

9.2.5.2.2 Evaluation of Results

9.2.5.2.3 Spectroscopy

9.2.5.2.4 Radionuclide Identification

9.2.5.3 Statistics

9.2.5.3.1 Minimum Detectable Activity (MDA)/Lower Limit of Detection (LLD)

9.2.5.3.2 Counting Time

9.2.5.3.3 Dead Time

9.2.6 Dose Assessment

9.2.6.1 Personnel Monitoring

9.2.6.1.1 Devices

9.2.6.1.2 Applicability

9.2.6.2 External

Attachment 2

9.2.6.2.1 Point/Line/Area/Volume Sources

9.2.6.2.2 Submersion

9.2.6.2.3 Hot Particles

9.2.6.3 Internal

9.2.6.3.1 Biological/Effective Half Life

9.2.6.3.2 Intake Retention Fraction (IRF)

9.2.6.3.3 Annual Limit on Intake (ALI)

9.2.6.3.4 Derived Air Concentration (DAC)

9.2.6.3.5 EPA Federal Guidance Report #11

9.2.6.3.6 ICRP-30

9.2.6.3.7 Medical Internal Radiation Dosimetry (MIRD)

9.2.6.4 Modeling

9.2.6.4.1 Use and Limitations

9.2.6.4.2 Types (RESRAD/COMPLY/MICROSHIELD/MIRDOSE etc

Attachment 3

9.3 Evaluation Of An Experienced Health Physicist For Core Competency (Section 8.2.2)

9.3.1 Name: _____

9.3.2 Date of Employment: _____

9.3.3 Date Health Physics Career began
(Technical or post K-12 schooling does not count): _____

9.3.4 Post K-12 Academic:

Colleges/University (Name/Degree/Date Completed): _____

_____

_____

9.3.5 Technical Schooling (Name/Course of Instruction/Date Completed): _____

_____

_____

9.3.6 Resume (application or C.V.) evaluation:

Areas worked and publications: _____

_____

_____

9.3.7 Certifications (other than C.H.P.)(Name/Date Granted): _____

_____

9.3.8 Basic Competency Test Administered: ____Yes____No Date Taken:_____

Passed: _____Yes_____No Score: _____

9.3.9 Certification

The following individual has been evaluated for the basic health physics competencies in accordance section 8.2.2 of this procedure. This individual has been found to be competent in basic health physics.

Name: _____ Date: _____

Signature: _____

Attachment 4

9.4 Non-NRC Sponsored Course Evaluation (Alternative Training) Form

9.4.1 Name of Evaluator _____

9.4.2 Course Name: _____

9.4.3 Proposed Equivalent NRC Course: _____

9.4.4 Do one or more of the following tasks:

9.4.4.1 Complete and attach to this form a table that compares the terminal and enabling objectives of the NRC course and the candidate course.

9.4.4.2 Complete and attach to this form a table that compares the key elements of the lesson plans for the NRC course and the candidate course.

9.4.4.3 Complete and attach to this form a table that compares the candidate course to the required training elements in reference 3.2 for the specialty area training being presented.

9.4.5 Reviewer Certification

9.4.5.1 Based on my examination of the training materials and comparisons done in section 9.4.4 above, I certify that the course named in section 9.4.2 above in equivalent to the NRC course in section 9.4.3 above.

9.4.5.2 Signature: _____ Date: _____

9.4.6 Supervising Health Physicist Certification

9.4.6.1 I have reviewed the materials presented by the reviewer and based on my professional judgment, I concur with the reviewer's certification in section 9.4.5 above.

9.4.5.2 Signature: _____ Date: _____

Attachment 5

9.5 Evaluation of Experience for Core Specialty Certification
(use one form for each Core Specialty Area.)

9.5.1 Name of Individual: _____

9.5.2 Core Specialty Area: _____

9.5.3 Name of Evaluator: _____

9.5.4 Evaluation

9.5.4.1 Years of experience in core specialty area: _____

9.5.4.2 Positions held: _____

_____

9.5.4.3 Major Duties: _____

_____

_____

9.5.4.4 Training Courses taken in area (Course Name/Date): _____

_____

9.5.4.5 Publications (List Titles Of Papers, Presentations, Training Courses, Etc and Date): _____

_____

9.5.4.6 Check sources of information below

___State Application ___Resume ___Interviews ___Certificates

9.5.6 Evaluator's Certification

9.5.6.1 Based upon my examination of the above individual's experience, I do___/___do not certify (check one) that this individual in qualified in the core specialty area listed in section 9.5.2.

9.5.6.2 Signature: _____ Date: _____

9.5.7 Supervising Health Physicist Certification

9.5.7.1 I do___/___do not concur with the above evaluation.

9.5.7.2 Signature: _____ Date: _____

Attachment 6

9.6 On-The-Job Training (OJT) Documentation

9.6.1 Name of Individual: _____

9.6.2 Core Specialty Area: _____

9.6.3 Name of Primary Trainer: _____

9.6.4 Selected Readings

9.6.4.1 The trainer shall prepare a table of selected readings for the OJT trainee. The readings will cover the following the sections of the following areas that pertain to the core specialty area (9.6.2):

9.6.4.1.1 Federal Law

9.6.4.1.2 Code of Federal Regulations (CFR)

9.6.4.1.3 California Code

9.6.4.1.4 California Code of Regulations (CCR)

9.6.4.1.5 US NRC Regulatory Guides

9.6.4.1.6 US NRC NUREG documents, information notices, and other NRC generated materials.

9.6.4.1.7 Technical articles, book chapters, internet resources, etc.

9.6.4.2 The trainer shall prepare a table with the selected readings above. The trainee shall read the information and initial the table as indicated to signify having read the information. The completed table will be attached to this form. The table shall have the following format:

Name of Document	Date Read	Initials

9.6.5 The trainer shall prepare a list of critical tasks for the core specialty area being trained. Critical tasks are those tasks that are considered key to demonstrating competence in the core specialty area. These tasks may be work assignments, problems, training exercises, etc. To the extent possible, the critical task should be performance based and reflect application in actual health physics situations.

9.6.5.1 Each task will have a title. For problems, training exercises, etc a complete description of the problem or training exercise will

documented and attached to the critical task form upon successful completion by the trainee.

9.6.5.2 The critical task list shall be in the form of a table (see the example in 9.6.5.3 below).

9.6.5.3 Sample Critical Task Table Format

Critical Task for Core Specialty Area:_____

Task Title	Date Completed	Trainee's Initials	Trainer's Initials

9.6.6 Critical Task Completion

9.6.6.1 The trainee shall do each critical task in three phases. The first phase the trainee will be an observer. The trainer may allow the trainee to do some "hands-on" work during this time. The trainer performs the task as many times as needed to assure the trainee can perform the task.

9.6.6.2 Once the trainer is satisfied that the trainee can perform the task, the trainee performs the task under direct supervision. The trainer must be physically present and able to observe the trainee's performance. The trainer may have the trainee repeat as many times as needed to assure that the trainee can perform the task under general supervision. In general supervision, the individual is not directly supervised and generally works independently. The supervisor's guidance is usually more general and less detailed. Note: I am not sure the intent of this paragraph but it is confusing in the use of “direct” and “general” supervision and “supervisor’s guidance” vice trainer. Aren’t you just trying to say that the trainee needs to perform the desired task while being observed by the trainer??

9.6.6.3 For the third phase, the trainee performs the task under the observation of the trainer. The trainer provides no directions, other than to stop the trainee is an unsafe condition occurs is about to occur. If the trainer is satisfied that the trainee can perform the critical task under general supervision(see comment above), then that task is considered complete. The completion date is entered on the Critical Task Table (see 9.6.5.3 above), and the trainee and trainer initial the form.

9.6.7 Certification of Completion of OJT

9.6.7.1 As the trainer named in section 9.6.3 of this document, I certify that the individual named in section 9.6.1 has completed the OJT training in the core specialty area listed in section 9.6.2.

9.6.7.2 Signature: _____ Date: _____

9.6.8 When all of the training has been completed, the original copy of this form and its supporting documents is filed with the Technical Training Coordinator, one copy is given to the trainee, and one copy is given to trainee's supervisor. The trainee's training journal is updated to reflect successful completion of the OJT.

ATTACHMENT G

CHANGES

1/4/08	Modified Section 9.1 to indicate that it is acceptable for the acting regional supervisor to review 5010s in the absence of the regional Senior in order to meet the two-week submittal criteria to Peggy.
12/29/07	Modified Section 16.10 to include information on doses to a nursing infant from I-131 administered to its mother.
12/7/07	Modified Section 13.3 to clarify that a NOVRUD is a non-legally binding document, and a licensee may legally cease compliance with the NOVRUD, after notifying RHB in writing.
11/30/07	Modified Section 9.9, Whistleblower Protection, to note RHB's obligation to notify potential whistleblowers of the CA Department of Industrial Relations whistleblower complaint procedure, and to document that this notification has been made in event narratives.
10/12/07	Added Section 7.6 to address conduct of pre-licensing visits for the purpose of enhanced security (i.e., to verify that radioactive materials will be used as intended), and to document those visits using a Pre-Licensing Visit Form.
1/9/07	Modified Section 13.3 to require notification of the CDHS Medical Officer before a medical facility is to be shut down as a result of the NOVRUD.
9/2/06	Modified Section 9.4 to provide a sample narrative format for allegations.
8/15/06	Modified Section 9.4 to address investigation narrative needs for allegations.
6/3/06	Added Section 17.13 to address Increased Controls inspector qualification requirements.

ATTACHMENT G

5/3/06	Revised sections 3.0, 5.0, 6.1, and 7.4 to note that the interval for conducting priority 6 inspections is 5 years (changed from 6 years).
8/31/05	Revised section 9.1 and added section 9.10 concerning notifying the SS&D and Special Projects Unit of RML of events affecting California issued SS&D sources/devices.
7/18/05	Revised section 9.4 guidance for investigation narratives.
4/20/05	Amended numbering in section 17.0 QUALIFICATION OF INSPECTORS to fix typographical errors.
3/28/05	Added Section 9.9 to address Whistleblower guidance. Also, guidance concerning announcing inspections was moved from Section 6.1 to Section 6.2; no changes were made in the guidance.
11/30/04	Numbered and revised Section 9.0 to incorporate guidance for 5010 forms concerning identification/notification requirements for California SS&D events and concerning using 5010 form to make 30-day NMED reports. (Also renumbered all sections after Section 9.0 to reflect the numbering of Section 9.)
11/29/04	Added Section 8.4 to address criteria for timely issuance of inspection documentation and a tracking system of track issuance times.
7/8/04	Revised section 7.3.1 concerning radiography inspections to require field radiography inspections for 50% of radiography operations performing field radiography, allowing field inspections in lieu of office inspections every other year, and specifying documentation criteria.

ATTACHMENT H

RECIPROCITY INSPECTIONS

Priority 1 – 3	**2004**	**2005**	**2006**	**2007**
No. Worked in CA	29	23	23	18
No. (and %) inspected	6 (21%)	10 (43%)	6 (26%)	8 (50%)
Priority 5 – 6				
No. Worked in CA	32	28	26	28
No. (and %) inspected	4 (13%)	2 (7%)	3 (12%)	5 (18%)

ATTACHMENT I

INSPECTOR ACCOMPANIMENTS

Inspector	Supervisor	License Category	Date
K. Furey	E. Gloor	Portable Gauge	11/9/05
"	K. Prendergast	Medical	2/9/06
"	R. Greger	Medical (IC)	7/12/06
"	K. Prendergast	Medical	12/27/07
M. Gottlieb	"	Irradiator (X-ray)	12/6/04
"	"	Nuclear Pharmacy	10/31/05
"	"	Radiography (IC)	7/31/06
"	"	Nuclear Pharmacy	2/12/07
K. A. Hewadikaram	"	Radiographer	1/14/05
"	"	Radiographer	12/8/05
"	"	Non-Medical	10/11/06
"	"	Radiographer	1/14/08
J. Hillman	E. Gloor	Medical	8/11/05
E. Mekuria	"	Radiographer (X-ray)	6/25/06
"	"	Non-Medical	2/28/07
D. Aquino	B. Hamrick	Radiographer (IC)	2/5/08
K. Harkness	"	Small Laboratory	6/14/06
"	"	Medical (IC)	8/25/06
D. Krajewski	K. Prendergast	Portable Gauge	10/27/05
"	B. Hamrick	Medical (IC)	10/12/06
"	J. Fassell	M&D	6/7/07
"	"	Fixed Gauge	1/24/08
A. Taylor	B. Hamrick	Portable Gauge	3/23/06
"	R. Greger	Radiographer (IC)	7/25/06
S. Doerfler	K. Kaufman	Nuclear Pharmacy	7/6/06
"	R. Greger	Medical (IC)	7/21/06
"	K. Kaufman	M&D	4/24/07
J. Ortego	K. Kaufman	Medical	2/28/06
R. Yonemitsu	R. Greger	Research Lab (IC)	9/14/06
S. Pay	E. Gloor	Radiography	9/21/05

ATTACHMENT J

LICENSING PROJECTS UNIT

Item number	Licensee	License Number	Date Action Complete	Action
1	PWN Environmental	3622	7/12/05 & 9/18/06	Implement Cease and Desist order and terminate – due to no Financial Surety
2	Dow Agrosciences	2179	4/7/06	Termination – C-14 in soil
3	RMD Operations	7542	4/21/06	New – U removal from drinking water, first ever issued as service provider type
4	Thermo Gamma Metrics	3775	5/8/06	Renewal – M&D
5	City of Ceres	7558	5/12/06	New – U removal from drinking water, first ever issued as possession only type
6	Excel Research	5863	9/5/06	Renewal – C-14 in soil
7	CPN Intl	1100	9/8/06	Renewal – M&D
8	General Atomics	0145	10/27/06	Renewal - Large scale D&D (Also, NRC licensee)
9	HIET	7127	10/1/07	Reauthorization - Coming out of bankruptcy
10	Kirk Rich Dial	0535	10/3/07	Termination – EPA superfund site, old radium watch dial site
11	JL Shepherd	1777	12/13/07	Renewal – M&D
12	ICN Biomedicals	7200	12/21/07	Termination – Multi-Nuclide Soil Contamination

ATTACHMENT K

MEDICAL AND ACADEMIC UNIT

Item number	Licensee	License Number	Date Action Completed	Action
1	UC Berkeley	1333	11/14/07	Renewal
2	UC Berkeley	1333	12/16/07	D&D of Warren Hall
3	Stanford University	0676	1/23/08	D&D of High Energy Physics Lab
4	Washington Hospital	1585	6/7/07	Addition of Perfexion Gamma Knife

ATTACHMENT L

State of California
Department of Health Services, Radiologic Health Branch
Procedure for Determining RML Inspection Priorities

Procedure Number:	**PRO 05-01**
Effective Date:	*February 7, 2008*
Supersedes:	RML 88-9
Prepared By:	Gonzalo L. Perez
Approved By:	Gary Butner
Related Document:	NRC Inspection Manual, Manual Chapter 2800
Procedure Title:	**Determining RML Inspection Priorities**

1.0 PURPOSE:

Assurance that the same priority code is assigned to all licenses which authorize a particular type of use.

2.0 APPLICABILITY AND SCOPE:

Inspection priority codes are assigned to particular types of use authorized by a radioactive material license.

3.0 REFERENCES:

1. Health and Safety Code Section 115070[1]
2. NRC Inspection Manual, Manual Chapter –2800
3. 17 CCR 30254 (a)

4.0 DEFINITIONS:

Inspection Priorities. The priority code (i.e., 1, 2, 3, or 5) is the interval between routine inspections, expressed in years. Enclosure 1 lists the program codes (types of use) along with the assigned priority codes. The priority represents the relative risk of radiation hazard for the type of use. Priority Code 1 presents the greatest risk to the health and safety of workers, members of the public, and the environment. Priority Code 5 presents less potential risk to health and safety . Because a license may authorize multiple types of use, the priority codes are designated as primary and secondary codes, with the shortest routine inspection interval as the primary code.

5.0 RESPONSIBILITIES:

5.1 License Reviewer

Assigns the primary program code which will set the inspection priority for each new license.

6.0 COMMUNICATION/DOCUMENTATION:

The following reference documents are available electronically:

Health and Safety Code @ www.leginfo.ca.gov

NRC Inspection Manual @ www.nrc.gov

[1] Health and Safety Code Section 115070 mandates that the frequency of inspections of radioactive materials be based on priorities established by the United States Nuclear Regulatory Commission.

7.0 FACILITIES, EQUIPMENT, SUPPLIES: none

8.0 PROCEDURE:

8.1 Determine the Primary Program in Attachment 1.

Select the primary program code listed in Attachment 1 by the activities authorized in the license. Set the inspection priority code for each new license based on this selection. Reviewers should note that some program codes show a designator (N). This designates the program code as not applicable (N) and should only be used as a secondary code.

8.2 If more than one program code.

Some licenses authorize activities that can be classified under more than one program code. If a license involves more than one type of use, each part of the program shall be inspected in accordance with its assigned priority. For example, a license for a medical institution (Program Code 02121, Priority Code 5) may be amended to authorize use of a high dose rate (HDR) remote after-loader unit (Program Code 02230, Priority Code 2). The licensee's primary program code would be Program Code 02230. The HDR-related activities would be inspected during every routine inspection while the other portions of the licensee's program would be inspected during every other routine inspection.

8.3 Data Entry

Upon issuance of a new license, the coding sheet is used to enter the inspection priority code number into the computer system. Amendments which change the inspection priority code number must be indicated on the coding sheet to update the computer system data.

The Senior Health Physicist for the unit responsible for the license type ensures that the coding sheet is given to the RML Operations Unit for data entry.

8.4 Exceptions

Upon approval by the Supervising Health Physicist individual licenses may be designated a higher priority (smaller number) than Attachment 1 stipulates. Examples where this can be done are cases where the radiation safety program is larger or more complex than the type indicates or the compliance history suggests a higher priority is warranted. These priority deviations and the rational associated with them must be documented in the licensing folder.

9.0 ATTACHMENTS:

Attachment 1: Inspection Priority Code Listing

Inspection Priority Code Listing

Program Code	Short Description	Inspection Priority Code
01130	Academic Other	5
01100	Academic Type A Broad	3
01110	Academic Type B Broad	5
01120	Academic Type C Broad	5
03241	Aircraft Safety Device GL Distribution - 30192.2	5
03242	Am-241GL Distribution - 30192.3	5
03710	Calibration and Check Source	5
03219	Decontamination Services	3
02259	Emerging Technology	2
03250	Exempt Distribution - Concentrations (NARM)	5
03253	Exempt Distribution - Small Quantities (NARM)	5
02210	Eye Applicators Strontium-90	3
03113	Field Flooding Studies	3
03240	Gauge GL Distribution - 30192.1	5
02230	High Dose Rate Remote After-loader	**3**
03243	Ice Detection Devices GL Distribution - 30192.4	5
03244	In Vitro Testing GL Distribution - 30192.5	5
02410	In Vitro Testing Laboratories	5
03235	Incineration - Noncommercial (Secondary Code)	N
03310	Industrial Radiography Fixed Location	2
03320	Industrial Radiography Temporary Job Sites	1
03222	Instrument Calibration Service, Greater Than 100 Curie	5
03221	Instrument Calibration Service, Less Than 100 Curie	5
02232	Intermittently Installed High Dose Rate Remote After-loader	2
02258	Intravascular Brachytherapy (Secondary Code)	2
03521	Irradiators Other Greater Than 10,000 Curies	2
03511	Irradiators Other Less Than 10,000 Curies	5
03520	Irradiators Self Shielded Greater Than 10,000 Curies	5
03510	Irradiators Self Shielded Less Than 10,000 Curies	5
03900	Large Scale Decommissioning of Facilities (No Source or SNM)	2
22200	Large Scale Decommissioning of SNM Facilities	2
11900	Large Scale Decommissioning of Source Material Facilities	2
03220	Leak Test Service	7
06101	Low Level Waste Storage (Secondary Code)	N
03214	Manufacturing and Distribution Other	5
03211	Manufacturing and Distribution Type A Broad	2
03212	Manufacturing and Distribution Type B Broad	5
03213	Manufacturing and Distribution Type C Broad	5

Program Code	Short Description	Inspection Priority Code
03800	Material Possession Only (No Source or SNM) - Permanent Shutdown	3
03810	Material Standby (No Source or SNM) - No Operations	3
03122	Measuring Systems Analytical Instruments	7
03120	Measuring Systems Fixed Gauges	5
03123	Measuring Systems Gas Chromatographs	7
03124	Measuring Systems Other	7
03121	Measuring Systems Portable Gauges	5
02250	Medical Group-1 (Secondary Code)	5
02251	Medical Group-2 (Secondary Code)	5
02252	Medical Group-3 (Secondary Code)	5
02253	Medical Group-4 (Secondary Code)	3
02254	Medical Group-5 (Secondary Code)	3
02255	Medical Group-6 (Secondary Code)	3
02256	Medical Group-7 (Secondary Code)	5
02257	Medical Group-9 (Secondary Code)	5
02120	Medical Institution - Major	3
02121	Medical Institution - Minor	5
02110	Medical Institution Broad	2
02200	Medical Private Practice - Major	3
02201	Medical Private Practice - Minor	5
02511	Medical Product Distribution - Prepared Radiopharmaceuticals	5
02513	Medical Product Distribution - Sources and Devices	5
02224	Mobile Diagnostic Client (Secondary Code)	5
02231	Mobile High Dose Rate Remote After-loader	2
02223	Mobile Nuclear Medicine Client (Secondary Code)	5
02220	Mobile Nuclear Medicine Service **Human Use**	3
02221	Mobile Nuclear Medicine Servive **Non-Human Use**	5
02240	Mobile Therapy	2
03218	Nuclear Laundry	3
02500	Nuclear Pharmacies	2
03225	Other Services	5
22162	Pacemaker - Manufacturing and Distribution	2
22160	Pacemaker - Medical Institution	7
02222	PET Mobile Client (Secondary Code)	5
22130	Power Sources	7
11700	Rare Earth Extraction and Processing	5
03620	Research and Development Other	5
03610	Research and Development Type A Broad	3
03611	Research and Development Type B Broad	5

Program Code	Short Description	Inspection Priority Code
03612	Research and Development Type C Broad	5
22170	SNM GL Distribution - 30192.3	5
22120	SNM Plutonium - Neutron Sources	5
22150	SNM Plutonium - Sealed Sources	5
22140	SNM Plutonium - Sealed Sources in Devices	5
22110	SNM Plutonium - Unsealed	3
23300	SNM Possession Only - Permanent Shutdown	2
23310	SNM Standby - No Operations	2
22151	SNM U-235 and/or U-233 Sealed Sources	5
22111	SNM U-235 and/or U-233 Unsealed	3
11230	Source Material GL Distribution - 30192.6	5
11300	Source Material Greater Than 150 kilograms	5
11200	Source Material Less Than 150 kilograms	5
11220	Source Material Military Munitions - Indoor Testing	5
11221	Source Material Military Munitions - Outdoor Testing	5
11800	Source Material Possession Only - Permanent Shutdown	2
11210	Source Material Shielding	7
11810	Source material Standby - No Operations	2
03215	SS&D Registry Certificate Holder (Secondary Code)	N
02310	Stereotactic Radiosurgery - Gamma Knife	2
02300	Teletherapy	5
03621	Tracer/Field Studies (Secondary Code)	5
25110	Transport - Private Carriage (Secondary Code)	N
02233	Transportable Service for High Dose Rate Remote After-loaders	2
02400	Veterinary Non-Human	5
03231	Waste Disposal (Burial)	2
03233	Waste Disposal Service Incineration	2
03232	Waste Disposal Service Prepackaged Only	3
03236	Waste Treatment Service (other than compaction)	2
03234	Waste Treatment Service Processing and/or Repackaging	2
03111	Well Logging Sealed Sources Only	3
03110	Well Logging Tracer and Sealed Sources	3
03112	Well Logging Tracers Only	3

Unit	LICENSEE	FACILITY	LICSTATUS	EXPIRDTE
I	0109	INST TECHNOLOGY	A	28-Aug-05
I	0196	INC.	A	30-Jun-05
I	0218	INC.	A	07-Jul-05
I	0377	PUBLIC HEALTH	A	30-Sep-99
I	0503	SRI INTERNATIONAL	A	14-Nov-99
I	0514	ANGELES/PUBLIC HEALTH LAB	A	23-Apr-06
I	0519	UNITED AIRLINES, INC.	A	19-Aug-00
I	0782	SERVICES	A	30-Jun-06
I	0799	TESTING, INC.	A	03-Sep-06
I	0809	RESEARCH INST.	A	06-May-05
I	1121	INC.	A	12-Sep-06
I	1417	OF CORONER	A	30-Jun-04
I	1450	AEROJET ORDNANCE COMPANY	P	01-Mar-05
I	1608	LAB, C/O CLPP BRANCH	A	28-Aug-06
I	1711	Q C SERVICES & ASSOCIATES	A	01-Jul-06
I	1898	TESTING ENGINEERS INC	A	04-Jun-04
I	2010	AEROTEST OPERATIONS, INC	A	25-Mar-05
I	2301	BAYER	A	28-Dec-04
I	2337	INC.	P	25-Aug-05
I	2375	CHEMISTRY/BIOLOGY	A	28-Jul-00
I	2510	CALIFORNIA	A	04-Apr-06
I	2900	WELENCO, INC	A	23-Oct-06
I	3531	AMERICA, INC	A	13-Dec-05
I	3940	DIAGNOSTICS INC.	A	24-Oct-99
I	4012	GILEAD SCIENCES	A	16-Apr-06
I	4224	SERVICES INC	A	12-Jan-00
I	4288	HEALTH SCIENCES	A	17-May-05
I	4498	PHARMACEUTICALS, INC	A	23-Sep-04
I	4618	PHILIPS LIGHTING COMPANY	A	16-Sep-06
I	4640	CENTER	A	27-Jan-06
I	4647	INC	A	23-Dec-06
I	4832	INSPECTIONS, INC.	A	01-Oct-05
I	4855	ANTICANCER, INC.	A	18-Dec-04
I	4886	MISTRAL HOLDING GROUP	A	30-Apr-06
I	4887	WRM CONSULTING	A	31-Mar-05
I	4948	CHAPMAN UNIVERSITY	A	15-Dec-05
I	4973	A. P. PHARMA, INC	A	16-Sep-05
I	5017	PTRL WEST INC	A	19-Nov-06
I	5118	GILEAD SCIENCES	A	13-May-06
I	5140	QUIDEL CORPORATION	A	29-Jun-06
I	5263	TECHNOLOGIES, INC.	A	31-Jan-06
I	5580	EQUINE REFERRAL SERVICE	A	25-Apr-05
I	5792	WESTMINSTER	A	28-Dec-99
I	5872	SCHOOL DISTRICT	A	07-Apr-00
I	5951	DIVISION	A	30-Aug-00
I	6032	GENZYME GENETICS	A	04-May-04
I	6034	ORANGE COUNTY	A	22-Jun-04
I	6089	EMAX LABORATORIES INC	A	03-Nov-04

Unit	LICENSEE	FACILITY	LICSTATUS	EXPIRDTE
I	6119	SERVICE INC	A	17-Apr-05
I	6125	ORANGE COAST TESTING, INC.	A	22-Jun-05
I	6148	FIBROGEN INC	A	28-Jun-05
I	6154	BIONIQUEST LAB SERVICES	A	23-Jun-05
I	6174	AMCYTE	A	19-Sep-05
I	6194	HEALTH LAB	A	18-Oct-05
I	6202	PACIFIC TECHNICAL SERVICES	A	19-Jan-06
I	6214	NUCLETRON CORPORATION	A	03-Oct-06
I	6269	INSTITUTE	A	29-Jul-06
I	6284	BAKER ATLAS	A	09-Sep-06
I	6301	MOTOROLA COMPANY	A	24-Oct-06
I	6336	SAN DIEGO, LLC.	A	03-Dec-06
I	6420	UNITED WIRELINE SERVICES	A	30-Dec-06
I	6481	SERVICES	A	09-Jul-05
I	7253	Kemia, Inc.	A	26-Jan-05
I	7377	CALIPERLIFE SCIENCES, INC	A	12-May-05
I	7461	WECK LABORATORIES, INC	A	19-Jul-05
I	7516	SIRION THERAPEUTICS	A	26-Jan-06
M	0060	LOMA LINDA UNIVERSITY	A	01-Apr-98
M	0061	KERN MEDICAL CENTER	A	19-Nov-04
M	0084	UNIVERSITY	A	07-Oct-96
M	0136	SAINT JOHN'S HEALTH CENTER	A	21-Feb-04
M	0165	MEDICAL CENTER	A	31-Mar-04
M	0208	HOSPITAL	A	29-Mar-04
M	0217	BEACH	A	07-Nov-97
M	0234	SERVICES	A	31-May-98
M	0237	CENTER	A	28-Jun-04
M	0246	MEDICAL CENTER	A	16-Feb-05
M	0261	O'CONNOR HOSPITAL	A	20-Apr-04
M	0272	PRESBYTERIAN	A	27-Jun-04
M	0276	INC.	A	13-May-04
M	0278	CENTER	A	11-Jun-05
M	0287	SAINT LUKES HOSPITAL	A	31-May-97
M	0307	RESEARCH INSTITUTE	A	28-Jun-06
M	0310	CHICO	A	03-Nov-05
M	0312	EL CAMINO HOSPITAL	A	26-Jun-97
M	0314	TECHNOLOGY	A	10-Mar-06
M	0332	POMONA COLLEGE	A	24-Feb-06
M	0372	CARE PROGRAM OF SO CALIF	A	24-Jun-98
M	0461	HOSPITAL	A	17-Oct-06
M	0485	CENTER	A	27-Jun-04
M	0488	ST. FRANCIS MEDICAL CENTER	A	28-Jun-98
M	0496	UNIV.- POMONA	A	12-Jul-04
M	0507	ST. JUDE MEDICAL CENTER	A	28-Jun-97
M	0508	REHABILITATION CENTER	A	05-Jun-97
M	0517	ALTA BATES MEDICAL CENTER	A	05-Jun-97
M	0566	BEVERLY HOSPITAL	A	22-Jul-04
M	0570	CENTER	A	28-Jun-97

Unit	LICENSEE	FACILITY	LICSTATUS	EXPIRDTE
M	0585	SANTA CLARA UNIVERSITY	A	10-Oct-05
M	0639	ANGELES	A	04-Mar-06
M	0670	GROSSMONT HOSPITAL INC	A	25-Jun-05
M	0687	SHARP MEMORIAL HOSPITAL	A	20-Apr-04
M	0696	HOSPITAL	A	11-Apr-04
M	0703	SACRAMENTO	A	08-Aug-96
M	0719	MERCY HOSPITAL	A	13-Aug-05
M	0764	MEDICAL CENTER	A	28-Jun-04
M	0788	HOSPITAL	A	15-Aug-04
M	0789	HOSPITAL	A	27-Aug-05
M	0840	UNIVERSITY OF THE PACIFIC	A	12-Aug-06
M	0901	MEDICAL CENTER	A	14-Apr-04
M	0976	SYSTEM, L.P.	A	27-May-04
M	0978	TENET CORPORATION, dba	A	12-Jun-01
M	1071	TRI-CITY MEDICAL CENTER	A	15-Feb-04
M	1276	CENTER	A	19-Nov-95
M	1290	CENTER	A	08-Mar-04
M	1333	BERKELEY	A	20-Sep-98
M	1339	CALIF-SAN DIEGO	A	01-Mar-06
M	1349	FULLERTON	A	30-Oct-95
M	1362	CALIF - RIVERSIDE	A	26-Apr-06
M	1368	LODI MEMORIAL HOSPITAL	A	21-Mar-05
M	1394	SAINT ROSE HOSPITAL	A	11-May-04
M	1404	HOLY CROSS MEDICAL CENTER	A	11-Jul-98
M	1418	HOSPITAL	A	12-Sep-00
M	1515	REGIONAL MED CENTER	A	07-May-04
M	1593	CATHOLIC HEALTHCARE WEST	A	24-Nov-04
M	1624	VALLEY HEALTH SYSTEM	A	04-Oct-05
M	1641	VALLEY	A	22-Jan-05
M	1652	SONOMA STATE UNIVERSITY	A	30-Apr-06
M	1670	GATOS, INC.	A	11-Mar-05
M	1703	SAINT JOSEPH HOSPITAL	A	23-May-06
M	1725	MEDICAL CNTR	A	12-Jan-06
M	1807	CENTER, INC	A	20-Nov-05
M	1827	MARIAN MEDICAL CENTER	A	23-Jan-06
M	1874	BERNARDINO	A	22-Apr-05
M	1948	CARE DIST/ ALAMEDA HOSPITAL	A	15-Oct-04
M	2012	GORUP, INC.	A	30-Mar-98
M	2017	OROVILLE HOSPITAL	A	28-Apr-06
M	2057	CARE PROGRAM OF SO. CAL.	A	08-Sep-00
M	2058	CARE PROGRAM	A	10-Aug-98
M	2120	HOSPITAL LP	A	24-Dec-04
M	2207	WALNUT CREEK CAMPUS	A	29-Jun-00
M	2236	HOSPITAL	A	04-Oct-04
M	2252	PACIFIC IMAGING	A	26-Oct-04
M	2282	FOUNTAIN VALLEY REGIONAL	A	09-Nov-04
M	2292	CENTER	A	07-Jan-04
M	2317	MARTIN LUTHER KING JR.-	A	23-Mar-04

Unit	LICENSEE	FACILITY	LICSTATUS	EXPIRDTE
M	2345	MODESTO, INC.	A	21-Apr-04
M	2353	MERCY MEDICAL CENTER	A	03-May-04
M	2390	CENTER, INC.	A	28-Aug-04
M	2430	HOSPITAL	A	30-Jan-04
M	2431	CORPORATION	A	01-Dec-04
M	2482	HOSPITAL	A	08-Feb-04
M	2483	PARADISE VALLEY HOSPITAL	A	03-Apr-04
M	2494	HOSPITAL	A	19-Mar-04
M	2502	HOSPITAL	A	27-Jun-05
M	2509	HOSPITAL	A	08-May-06
M	2530	HOSPITAL	A	05-Jun-05
M	2573	SACRAMENTO	A	15-Sep-06
M	2578	EMANUEL MEDICAL CENTER	A	23-Aug-05
M	2583	HOSPITAL	A	18-Dec-04
M	2590	- HAYWARD	A	18-Jan-96
M	2617	CARE PROGRAM	A	22-Jan-96
M	2625	HOSPITAL	A	30-Nov-04
M	3097	NORTH BAY MEDICAL CENTER	A	03-Nov-04
M	3153	CHINESE HOSPITAL	A	22-Apr-04
M	3162	STANISLAUS CNTY	A	11-Apr-04
M	3192	HOSPITAL	A	09-Jun-04
M	3223	Hospital	A	02-Mar-04
M	3271	HOSPITAL	A	18-Jan-05
M	3274	HOSPITAL	A	05-Jan-04
M	3309	CENTER	A	13-Apr-04
M	3317	dba: CARDINAL HEALTH	A	14-Mar-04
M	3382	HOSPITAL	A	14-Sep-05
M	3384	HOSPITAL DISTRICT	A	26-Sep-04
M	3415	HOSPITAL, INC.	A	26-Dec-05
M	3426	CARDIANL HEALTH	A	29-Jan-05
M	3442	HOSPITAL, LP	A	06-Mar-05
M	3513	SANTA ROSA	A	21-Feb-96
M	3653	GROUP INC	A	03-Mar-05
M	3655	ONCOLOGY CENTERS, INC.	A	03-Jul-05
M	3666	IMAGING CENTER	A	28-Mar-05
M	3701	CENTER, INC.	A	25-Jul-04
M	3704	RADIOLOGY TECHNICAL	A	21-Jul-05
M	3834	HOSPITAL	A	13-Apr-06
M	3981	CENTER	A	16-Nov-05
M	4199	GROUP	A	05-Aug-00
M	4298	RADNET MANAGEMENT, INC.	A	18-Jan-05
M	4313	PACIFIC MEDICAL IMAGING, INC.	A	07-May-98
M	4327	OF SOUTHERN CAL	A	15-Feb-05
M	4511	MYINT, U SOE, MD	A	09-Jan-04
M	4547	SPECIALIZED IMAGING, INC	A	05-Aug-04
M	4615	MEDICAL CENTER	A	21-Oct-04
M	4643	FOUNDATION	A	09-Sep-04
M	4672	DIAGNOSTIC CENTER	A	09-Dec-00

Unit	LICENSEE	FACILITY	LICSTATUS	EXPIRDTE
M	4779	Rosa	A	25-Aug-04
M	4795	SOUTHERN CALIF	A	16-Dec-04
M	4809	HEALTHCARE	A	05-Sep-06
M	4810	HEALTHCARE	A	23-Apr-04
M	4811	HEALTHCARE	A	11-Sep-04
M	4839	CENTER	A	09-Oct-05
M	4853	dba: CARDINAL HEALTH	P	24-Apr-05
M	4861	VACAVALLEY HOSPITAL	A	01-Jul-04
M	4898	MANTECA,INC	A	28-Jan-06
M	4905	CARDINAL HEALTH, 414, INC.	A	02-Jul-05
M	4930	VALLEY HEART ASSOCIATES	A	12-Jan-06
M	4941	MEDICAL GROUP	A	29-May-04
M	4944	CARDIOVASCULAR INSTITUTE	A	04-Jun-04
M	4951	DON D CHO, MD	A	10-Nov-05
M	4999	DBA: CARDINAL HEALTH	A	24-Nov-04
M	5139	TREATMENT CENTER	A	04-May-06
M	5179	MODERN NUCLEAR, INC	A	07-Mar-96
M	5325	THOUSAND OAKS	A	23-Apr-97
M	5433	INC.	A	24-Apr-97
M	5508	MEDICAL GROUP INC	A	26-Oct-97
M	5597	INLAND IMAGING SERVICE	A	09-Mar-99
M	5616	ASSOCIATES MEDICAL GROUP	A	24-Jun-98
M	5724	ADVANCED MEDICAL IMAGING	A	06-Feb-99
M	5766	FACILITY STOCKTON	A	22-Jul-99
M	5993	MEDICAL GROUP	A	04-Jan-04
M	6017	MARIN	A	23-Mar-04
M	6046	CENTER	A	25-Apr-04
M	6055	DESERT VALLEY HOSPITAL	A	01-Sep-04
M	6069	DIS	A	20-Jun-04
M	6072	SAN DIEGO GAMMA KNIFE LP	A	29-Jul-04
M	6086	OF NAPA VALLEY	A	21-Sep-04
M	6117	HEMET HEART CENTER	A	25-Dec-04
M	6152	INC.	A	26-Jul-05
M	6188	PAIN CENTER	A	04-Jan-06
M	6205	ASSOCIATES	A	13-Dec-05
M	6215	MEDICINE MEDICAL GRP	A	29-Dec-05
M	6218	GROUP	A	11-Dec-05
M	6224	VISTA INC.	A	12-Mar-06
M	6235	IMAGING MEDICAL GP	A	20-Jun-06
M	6245	CARDIOVASCULAR IMAGING	A	04-Jun-06
M	6264	ISORX	A	04-Sep-06
M	6265	CARDIOVASCULAR GROUP	A	16-Aug-06
M	7401	DBA	A	08-Jun-05
M	7424	IMAGING, INC.	A	19-Apr-05
M	7431	MRI & DIAGNOSTIC IMAGIN	A	13-Sep-05
P	0011	COMPANY	A	31-Oct-04
P	0015	SUSANA FIELD LABORATORY	A	11-Sep-05
P	0065	THE BOEING COMPANY	A	21-Jun-00

Unit	LICENSEE	FACILITY	LICSTATUS	EXPIRDTE
P	0075	FOUNDRY COMPANY, LLC	A	07-Dec-06
P	0190	THE DOW CHEMICAL COMPANY	A	01-Mar-05
P	0256	SYSTEMS	A	17-Apr-05
P	0441	BECKMAN COULTER, INC	A	02-Aug-05
P	0531	DIVISION OF ENG. SERVICES	A	21-Jan-05
P	0748	HALACO ENGINEERING CO	P	12-Aug-76
P	0894	PUBLIC WORKS	A	21-Apr-05
P	1025	VARIAN MEDICAL SYSTEMS, INC.	A	25-Nov-97
P	1196	MGMT DISTRICT	A	18-Feb-06
P	1313	BECKMAN INSTRUMENTS INC	A	02-Aug-05
P	1451	INC.	A	31-Dec-04
P	1509	PRODUCTS, INC.	A	08-Jun-01
P	1544	TRANSPORTATION-DISTRICT 11	A	21-Apr-00
P	1563	WORKS	A	09-Jun-04
P	1586	INDUSTRIAL DYNAMICS CO LTD	A	26-May-04
P	1599	LABORATORIES	A	23-Aug-04
P	1616	CAL TRANS - DISTRICT 9	A	06-Oct-00
P	1639	CONSULTING, INC.	A	15-Dec-04
P	1752	DEPT OF PUBLIC WRKS	A	06-Sep-04
P	1777	J. L. SHEPHERD & ASSOCIATES	A	09-Oct-95
P	1828	MP BIOMEDICALS	P	19-Mar-06
P	1933	NDC INFRARED ENGINEERING	A	31-Dec-04
P	1947	RMC PACIFIC MATERIALS, INC.	A	20-Nov-06
P	1995	ENGINEERS, INC.	A	18-Feb-99
P	2026	PUBLIC WORKS	A	13-Jul-05
P	2198	DIVISION	A	18-Jun-04
P	2336	M-H-M,INC.	A	21-Apr-00
P	2402	ANALYSIS INC	A	03-Oct-05
P	2427	INC	A	02-Oct-05
P	2484	Advanced Tech. Corp.	A	05-Feb-98
P	2563	SANTA BARBARA	A	24-Aug-05
P	2611	WORKS DEPT.	A	27-Dec-04
P	2689	SIERRA PINE LTD	A	03-May-06
P	2706	Humboldt Flakeboard Panels, Inc.	A	12-Aug-06
P	2758	AGENCY	A	05-Sep-06
P	2777	CITY OF NEWARK	A	06-Oct-06
P	2828	ENGINEERING DEPARTMENT	A	25-Feb-06
P	2831	COUNTY OF MENDOCINO	A	27-Feb-06
P	2877	CELITE CORPORATION	A	18-Jul-06
P	2917	DIAGNOSTIC PRODUCTS CORP	A	14-Mar-06
P	3092	VARIAN, INC.	A	17-Apr-05
P	3109	LEIGHTON AND ASSOCIATES	A	21-Dec-98
P	3194	DELLAVALLE LABORATORY, INC.	A	13-May-00
P	3229	MOUNTAIN PASS MINE	A	05-Aug-98
P	3390	INC.	A	29-Jan-06
P	3511	YREKA CONSTRUCTION, INC.	A	16-May-00
P	3616	COUNTY/COMMUNITY	A	12-Mar-04
P	3665	LA DEPT OF WATER & POWER	A	10-Apr-05

Unit	LICENSEE	FACILITY	LICSTATUS	EXPIRDTE
P	3694	CONSUL	A	10-Oct-04
P	3755	CORPORATION	A	12-Mar-06
P	3763	ASSOCIATES	A	08-Dec-06
P	3823	CORPORATION	A	11-Mar-06
P	3836	MATERIALS	A	11-May-06
P	3924	GEOCON INC	A	09-Aug-05
P	3953	REFLEX INDUSTRIES	A	26-Jan-97
P	4145	CLEARY CONSULTANTS, INC	A	13-Dec-06
P	4823	GLOBAL FIRE AND SAFETY, INC.	A	23-Oct-04
P	4868	INC.	A	26-Dec-00
P	4873	BIG WEST OF CALIFORNIA, LLC	A	02-Jun-04
P	4888	CENCO REFINING COMPANY	A	12-Jan-04
P	4900	TAYLOR, JIM	A	09-Mar-04
P	4925	Analytics	A	11-Mar-04
P	4988	SERVICES INC	A	30-Sep-04
P	4992	INC	A	10-Sep-04
P	5016	ENGINEERING	A	26-Oct-04
P	5162	URS CORPORATION	A	17-Oct-05
P	5176	CENTRAL VALLEY TESTING, INC.	A	07-Jul-05
P	5184	JAE H YANG	A	19-Oct-05
P	5212	TECHNOLOGIES INC	A	19-Oct-05
P	5246	SOILS SOUTHWEST, INC.	A	19-May-06
P	5295	FRANK LEE AND ASSOCIATES	A	22-Aug-06
P	5339	GEOSYNTEC CONSULTANTS	A	20-Jul-06
P	5497	INC.	A	30-Aug-97
P	5770	GEOTESTING SERVICES	A	14-May-00
P	5827	SERVICES	A	27-May-00
P	5894	INC	A	05-Apr-00
P	5916	BROWN & MILLS INC	A	17-May-00
P	5933	INC.	A	03-Nov-04
P	6044	VITRAX	A	10-Jun-04
P	6061	R J R ENGINEERING GROUP	A	23-Jun-04
P	6122	INC.	A	30-Jan-05
P	6163	LLC	A	20-Jul-05
P	6187	SERVICES, INC.	A	16-Nov-05
P	6191	CARLTON ENGINEERING INC	A	28-Sep-05
P	6192	ISI INSPECTION SERVICES, INC	A	28-Sep-05
P	6199	INCORPORATED	A	14-Nov-05
P	6211	LABORATORIES, INC.	A	06-Dec-05
P	6226	FONTANA PAPER MILLS, INC.	A	09-May-06
P	6232	CENTER INC	A	17-Apr-06
P	6238	SASSAN GEOSCIENCES, INC	A	05-Mar-06
P	6258	GSI SOILS, INC.	A	09-May-06
P	6263	SUB-SURFACE DESIGNS	A	17-May-06
P	6271	(ESE LLC)	A	21-Jun-06
P	6275	INC	A	09-Sep-06
P	6318	SLADDEN ENGINEERING	A	18-Nov-06
P	6326	LABORATORIES	A	08-Nov-06

Unit	LICENSEE	FACILITY	LICSTATUS	EXPIRDTE
P	6327	KORBMACHER ENGINEERING	A	01-Dec-06
P	6329	CONSULTANTS INC	A	17-Dec-06
P	6345	AZ GEOTECHNICS, INC.	A	31-Dec-06
P	A001	LEHR	P	07-Feb-03
P	A002	Ascon	P	07-Feb-03
P	A003	Otay	P	07-Feb-03
P	A004	Porta Bella LLC	P	07-Feb-03
P	A005	ETEC	P	07-Feb-03
P	A006	Nucor Corporation, Inc.	P	13-Feb-03

ATTACHMENT N

The Licensing Projects Unit identified three Sealed Source and Device issues to report during this IMPEP review period. For additional information on any of these events, please talk to the contact person:

EVENT 1:
CONTACT: Ron Rogus

SSD identifier: CA0661D103S
Varian Medical Systems, Inc. (distributor)
Models VariSource and VariSource iX

Issue: Part 21 generic defect with the Model VariSource.

Initiating event 7/15/07: Event at City of Hope / Beckman Research Institute (LN0307-19) located in Duarte, CA. Event date was Sunday, 7/15/07. Rogus initiated 5010 on 7/16/07. Physicist turned the emergency retract handle in an effort to retract the dummy wire. Turning the handle pulled the active wire out of the safe. The wire could not be returned to the safe. Vault secured. Recovery operation needed.

NMED search and interviewing of licensee and Varian Medical Systems personnel. Four similar events were found over the past 3 years.

NRC reportable event. On 7/16/07, Rogus faxed 5010 and Dr Han's report to the NRC Ops Ctr.

City of Hope Report. Refer to Event Report, dated 7/17/07, by Chuck Pickering, RSO.

NRC/CA coordination. Rogus worked with NRC (John Jankovich) and State Agreements Officer (Randy Erickson).

7/30/07 RHB inspected City of Hope. RHB staff (Kauffman, Doerfler, Rogus). City of Hope staff (Pickering, Han, Schultheiss). Varian Medical Systems staff (Piccolo). Broad inspection of event.

9/6/07 NRC inspected Varian's Corporate office in Charlottesville, VA. NRC (Jankovich and Cynthia Flannery). Varian (Piccolo). Virginia (Mike Welling).

9/17/07 Varian's Part 21 event report – revised initial notification – submitted to NRC Operation's Center.

10/17/07 NRC issued NRC INFORMATION NOTICE 2007-35 regarding VariSource HDR events with Ir-192 source pulled from shielded position.

12/27/07 5010 at City of Hope closed out.

ATTACHMENT N

1/7/08 RHB issued Radiation Safety Advisory 08-01. Attached NRC INFORMATION NOTICE 2007-35.

1/30/08 CA issued amendment to VariSource SSD. SSD covers new warning label on emergency retract handle, discussion of emergency retract handle function and safety, reference to Varian Customer Technical Bulletin, and Varian commitments regarding additional emphasis on emergency retract training. Varian committed to working on engineering redesign.

EVENT 2:
CONTACT: John Fassell

Stork Materials Incident: Source Disconnect of 11/6/2007

On 11/6/2007 a source disconnect occurred at Commercial Metals in Orange, CA involving radiography equipment owned by Stork Materials and Inspection (RAML# 1880-19). The equipment was a Amersham 660B camera with a YDA25 crank assembly. The YDA25 designation is not specified in the SSD for Amersham 660B camera but is specified as a parts designation on the Industrial Nuclear Corporation website. The crank assembly was ordered as part of an order of two such assemblies from American NDT Products on 4/24/07 and shipped on 5/1/07.

After the failure of one of the crank assemblies while in service the other was tested and also failed. Further research during the 11/15/07 investigation indicated their could be a Part 21 issue with this device combination since all parties involved claimed to have tested their respective pieces of the supply chain and that they were okay.

LPU was made aware of all steps of the investigation by Barbara Hamrick by direct conversation. It was an ongoing investigation until 2/22/08 when an e-mail was received from Barbara Hamrick stating that the RSO of Stork Materials had called to say that INC had determined that clamshell pieces on the drive adapter provided to Stork Materials were not the proper ones for the Amersham 660B camera. This demonstrates that it is not a Part 21 defect requiring revision of the SSD but is a matter of determining if INC or American NDT is at fault for providing improper materials. The investigation is still ongoing in that aspect.

The interim investigation report required to the NRC has not been provided within the required 60 day timeline but will be by 3/10/08. (due 1/5/08)

EVENT 3:
CONTACT: John Fassell

ATTACHMENT N

Beckman Coulter: Ongoing since 1993 LS5800/6500 leaking LSC sources

Since 1993 reports have been received from all over the USA of leaking 30 microcurie sources in Beckman Coulter LS5800/6500 liquid scintillation counters. In 2003 the State of California finally made a concerted effort to solve the problem. A root cause investigation determined that inadequate source manufacturing techniques of the Model 598860 source which was unique to the CA0181D101G registry caused an early failure of these sources. A registry modification adding a useful life limit of 8 years was added to the registry on 5/11/06 and Beckman Coulter was required to notify all their users of the problem. Beckman Coulter is also going to each LSC at its required periodic maintenance inspection and replacing these sources. By 2011 all such sources should be replaced. NRC and Agreement states were notified shortly after 5/11/06 of this resolution vis the SSD issuance process and posting to the NRC SSD website.

This document to be used with the SRS list of April 23, 2007, tracking ticket number: 7-34.

STATE REGULATION STATUS
State Name

(# license condition reviewed is identified by a ★ at the beginning of the equivalent NRC requirement.)

Tracking Ticket Number:
Date:

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F)[i] Rule / ML #[5]	NRC Review / Y, N[ii] / Date / ML #[5]	Final State Regulation[1] (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1			Superceded by 1997-5
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Superceded by 1997-5
Standards for Protection Against Radiation-Part 20	56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94)	1991-3			
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4			
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1			Superceded by 2002-2
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30, 35	57 FR 45566; (none)	1992-2			Not required[3]
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1			
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			Review sheet not available[4]
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Review sheet not available[4]
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1			Not required[3]

This document to be used with the SRS list of April 23, 2007, tracking ticket number: 7-34.

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F)[i] Rule / ML #[5]	NRC Review / Y, N[ii] / Date / ML #[5]	Final State Regulation[1] (Effective Date)
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3			
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767; 59 FR 65243 60 FR 322; (1/1/98)	1995-1			
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2			
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3			
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4			Superceded by 1997-5
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5			
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6			
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7			Superceded by 2002-2 and 2005-2
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724 (4/1/99)	1996-1			Superceded by 2004-1
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required[3]
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3			

This document to be used with the SRS list of April 23, 2007, tracking ticket number: 7-34.

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F)[i] Rule / ML #[5]	NRC Review / Y, N[ii] / Date / ML #[5]	Final State Regulation[1] (Effective Date)
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1			
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2			DPH-07-002: With Office of Regulations.
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3			
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Superceded by 2004-1
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5			R-25-03 Submitted to OAL on 2-29-08. OAL approval deadline is April 14, 2008.
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6			
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7			Completed 8-27-06.
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1			Completed 1-28-06.
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required[3]
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Superceded by 2002-2

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Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4			See 1997-5.
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998-5			
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6			
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			Not required[3]
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3			Completed 8-19-06.
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1			Completed 3-31-07.
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2			Part 34: See 1997-5.
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1			
Revision of the Skin Dose Limit -Part 20	67 FR 16298; (4/5/05)	2002-1			
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (10/24/05)	2002-2			Part 35: DPH-05-018: In development.
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327; (12/3/06)	2003-1			DPH-06-018: Budget and Legal review as of 3-5-08.
Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments - Part 71	69 FR 3697; (10/01/07)	2004-1			DPH-07-008: Budget and Legal Review as of 3-5-08. SA-200 letter to be mailed

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					for initial review.
Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1			
Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; (4/29/08)	2005-2			Part 35: DPH-05-018: In development.
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090)[6]	70 FR 72128;(12/1/05)	2005-3			
Minor Amendments-Parts 20, 30, 32, 35, 40 and 70	71 FR 15005 (3/27/09)	2006-1			
National Source Tracking System - Serialization Requirements - Part 32 with reference to Part 20 Appendix E	71 FR 65685 (2/6/07)	2006-2			
National Source Tracking System - Part 20[7]	71 FR 65685 (11/15/07) & (11/30/07)	2006-3			

1. Or other generic Legally Binding Requirements.

2. (Y/N) Y means "Yes," there are comments in the review letter that the State needs to address.
N means "No," there are no comments in the review letter.

3. Not Required means these regulations are not required for purposes of compatibility.

4. A State need not adopt a specific regulation if the State has no licensees that would be subject to the regulation. See: "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," III.1.Time From For Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.

5. ADAMS ML Number.

6. By letter dated September 2, 2005, from Paul H. Lohaus, Director, Office of State and Tribal Programs, Agreement States were given 90 days to issue legally binding requirements satisfying the requirements of NRC Order EA-05-090.

7. RATS ID 2006-3 will not be considered under the Non-Common Performance Indicator "Compatibility Requirements" for IMPEP reviews until such time as the National Source Tracking System is ready for use Revisions in the implementation date for Agreement States will

This document to be used with the SRS list of April 23, 2007, tracking ticket number: 7-34.

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be provided to the States under separate correspondence and the SRS sheet will be revised as appropriate.

State: California **Tracking Ticket Number: 7-34**
[1 Amendment reviewed is identified by a ★ at the beginning of each equivalent NRC regulation] **Date: April 23, 2007**

NRC Chronology Identification	FR Notice (Date Due For State Implementation)	RATS ID	Proposed (P) / Final (F)[1] Rule / License Condition (LC) ML #[5]	NRC Review / Y, N[2] / Date / ML #[5]	Final State Regulation[1] (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	P ML051580164	N 10/13/05 ML052870320	Partial Submittal-only requirements of Part 34 reviewed
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required[3]
Standards for Protection Against Radiation-Part 20	56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94)	1991-3	F ML020030346	N 3/18/02 ML020780186	11/14/01
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F	N 4/1/98	9/9/97
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1			
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2			Not required[3]
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1	F ML022140223	Y 8/22/02 ML022350054	
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	LC ML051670371	N 7/1/05 ML051810407	
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not applicable SECY-95-112[4]

NRC Chronology Identification	FR Notice (Date Due For State Implementation)	RATS ID	Proposed (P) / Final (F)[1] Rule / License Condition (LC) ML #[5]	NRC Review / Y, N[2] / Date / ML #[5]	Final State Regulation[1] (Effective Date)
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618; (none)	1994-1	F	N 4/1/98	9/9/97 Not required[3]
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			Not applicable SECY-95-112[4]
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3			
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767; 59 FR 65243; 60 FR 322; (1/1/98)	1995-1	F	N 11/16/99	11/12/99
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F ML020030346	N 3/18/02 ML020780186	11/14/01
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983; (3/1/98)	1995-3	F ML020030346	N 3/18/02 ML020780186	11/14/01
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	P ML051580164	N 6/30/05 ML051810453	
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F ML020030346	N 3/18/02 ML020780186	11/14/01
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F	N 4/1/98	9/9/97
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7			

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10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724; (4/1/99)	1996-1			
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required[3]
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F ML020030346	N 3/18/02 ML020780186	11/14/01
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1	F ML020030346	N 3/18/02 ML020780186	11/14/01
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2	F ML022140223	Y 8/22/02 ML022350054	
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F ML020030346	N 3/18/02 ML020780186	11/14/01
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required[3]
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5	P ML051670371	Y 10/13/05 ML052870320	
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F ML020030346	N 3/18/02 ML020780186	11/14/01
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7	P ML060250530 ML061360365	N 06/19/06 ML061700392	

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Deliberate Misconduct by Unlicensed Persons- Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1	F ML060340073	N 3/9/06 ML060670437	
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required[3]
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required[3]
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	P ML051670371	Y 10/13/05 ML052870320	
Minor Corrections, Clarifying Changes, and a Minor Policy Change- Parts 20, 35, 36	63 FR 39477; 63 FR 45393; (10/26/01)	1998-5	F ML020030346	N 3/18/02 ML020780186	11/14/01
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F ML020030346	N 3/18/02 ML020780186	11/14/01
Radiological Criteria for License Termination of Uranium Recovery Facilities- Part 40	64 FR 17506; (6/11/02)	1999-1			Not applicable SECY-95-112[4]
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information- Part 31	64 FR 42269; (none)	1999-2			Not required[3]
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524; (2/2/03)	1999-3	F ML062210438	N 8/31/06 ML062490010	
⋆Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML070920384	N 4/23/07 ML071140038	

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New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	P ML051580164ML061790298 LC ML061790298	N 7/17/06 ML061990575 N 7/17/06 ML061990575	Partial Submittal - Only requirements of Part 39 reviewed (PN 06/30/05) Part 36 adopted by reference
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	LC for 32.52 (a) & (b) ML003696531	N 3/10/04 ML040500440	02/25/04
Revision of the Skin Dose Limit-Part 20	67 FR 16298; (4/5/05)	2002-1	F ML062210438	N 8/31/06 ML062490010	1/30/06
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (10/24/05)	2002-2	F ML062210438	N 8/31/06 ML062490010	Partial submittal-only requirements of Part 20 reviewed (1/30/06)
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327; (12/3/06)	2003-1			
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71	69 FR 3697; (10/01/07)	2004-1			

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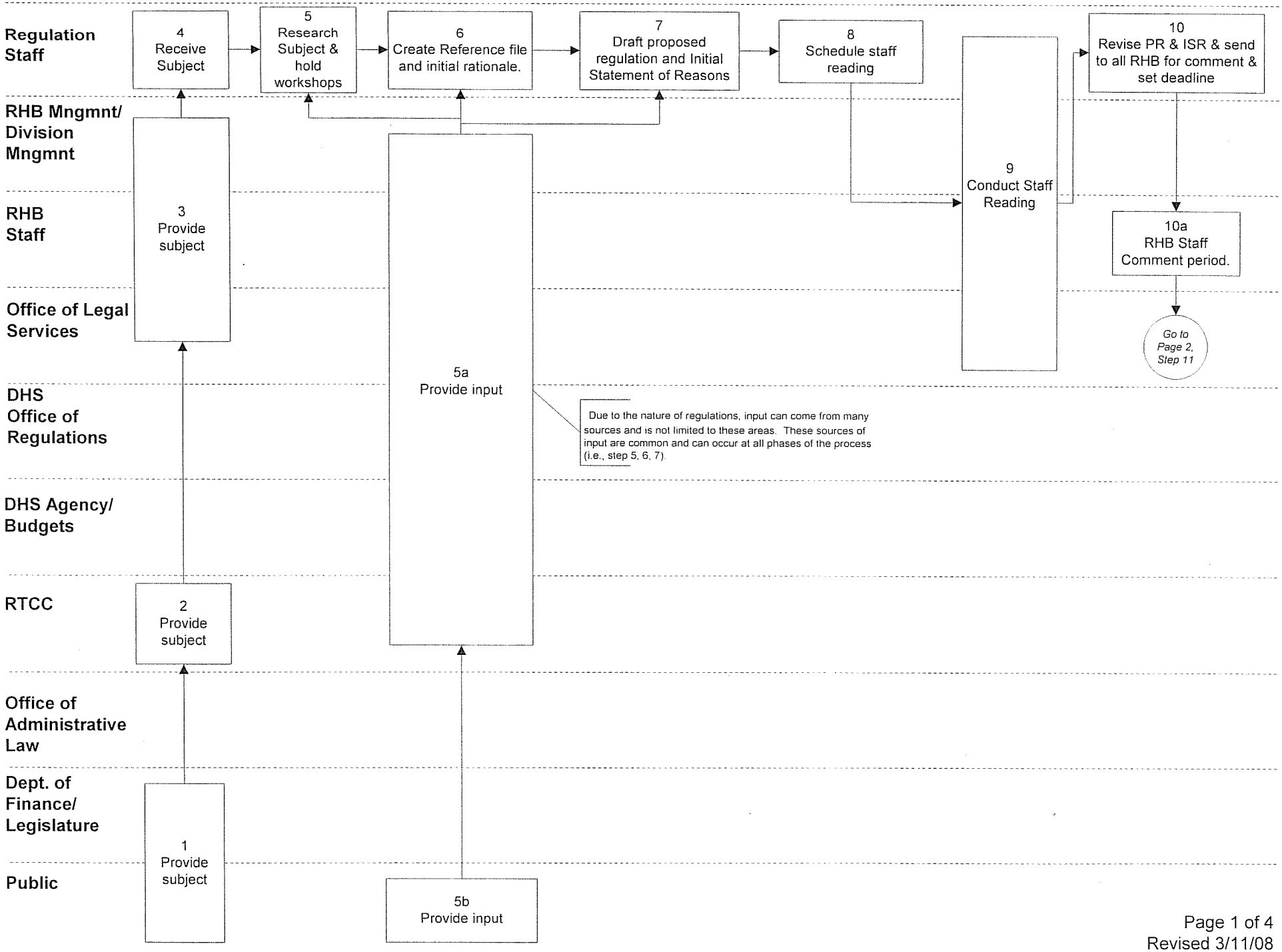
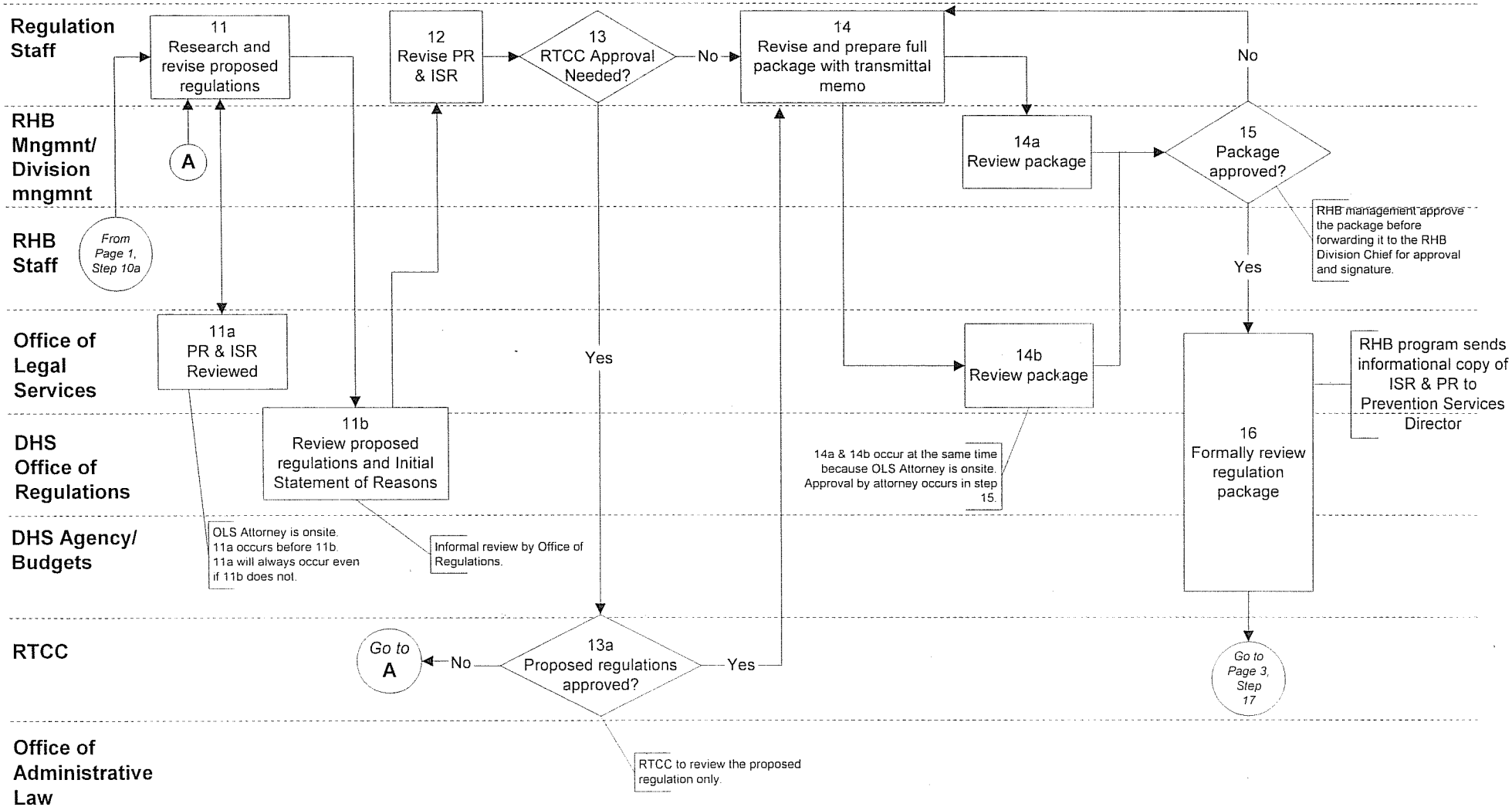
Security Requirements for Portable Gauges Containing Byprodcut Material - Part 30	**70 FR 2001; (7/11/08)**	**2005-1**	**LC ML062920179**	**N 11/09/06 ML063130004**	
Medical Use of Byproduct Material - Recognition of Speciality Boards - Part 35	**70 FR 16336; 71 FR 1926 (4/29/08)**	**2005-2**			
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090)[7]	**70 FR 72128; (12/1/05)**	**2005-3**	**LC ML053060120**	**N 11/04/05 ML053080246**	
Minor Amendments - Part 20,30,32,35,40 and 70	**71FR15005 (3/27/09)**	**2006-1**			
National Source Tracking System - Serialization Requirements - Part 32 with reference to Part 20 Appendix E	**71 FR 65685 (2/6/07)**	**2006-2**	**LC ML070460575**	**N 02/16/07 ML070470007**	
National Source Tracking System - Part 20	**71 FR 65865 (11/15/07) & (11/30/07)**	**2006-3**			

1. Or other generic Legally Binding Requirements.
2. (Y/N) Y means "Yes," there are comments in the review letter that the State needs to address. N means "No," there are no comments in the review letter.
3. Not required means these regulations are not required for purposes of compatibility.
4. A State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. See: "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," III.1. Time Frame for Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
5. ADAMS ML Number
6. By letter dated September 2, 2005, from Paul H. Lohaus, Director, Office of State and Tribal Programs, Agreement States were given 90 days to issue legally binding requirements satisfying the requirements of NRC Order EA-05-090.

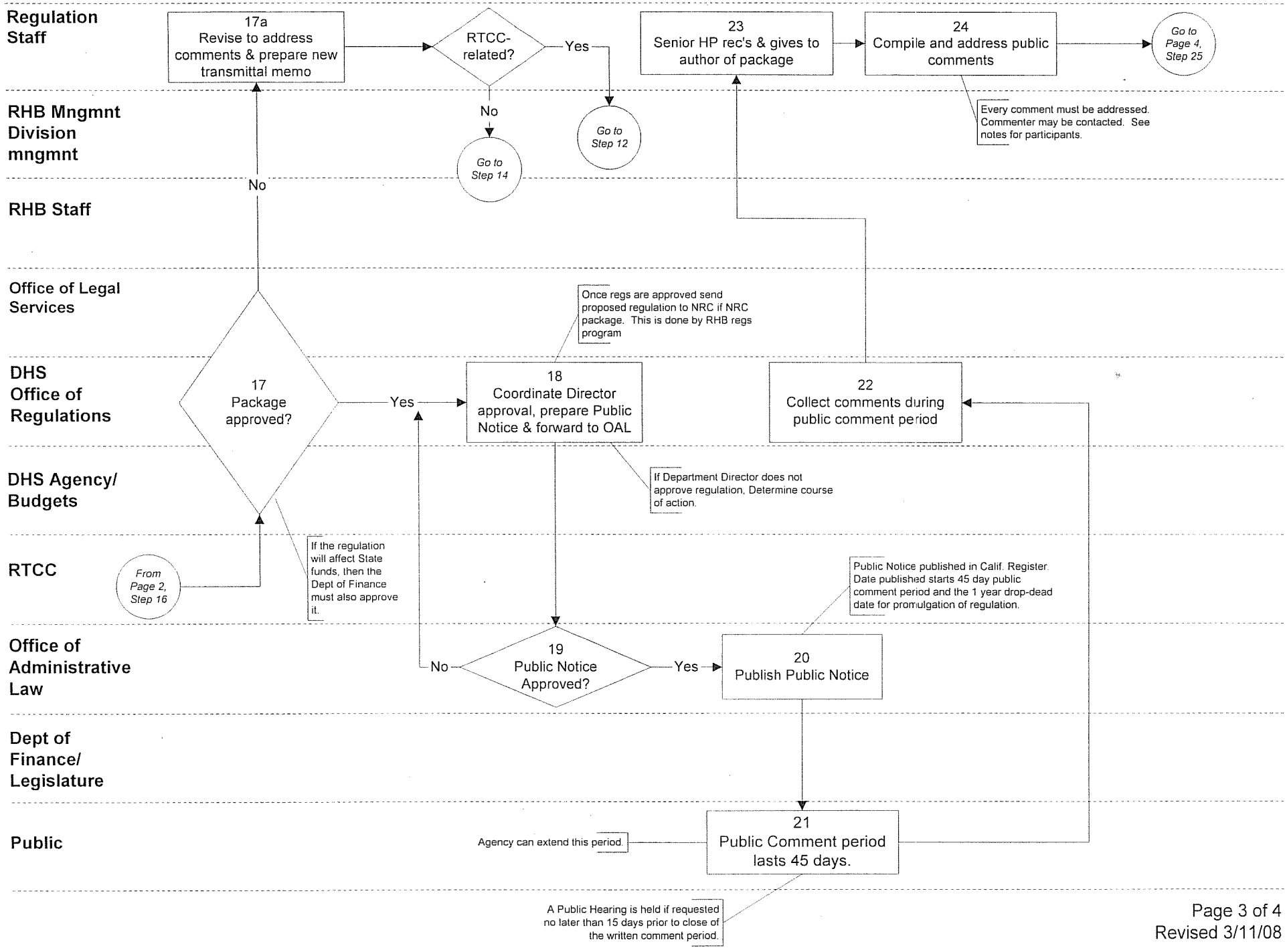
Regulatory Process



Regulatory Process



Regulatory Process



Regulatory Process

Regulation Staff

RHB Mngmnt/ Division mngmnt

RHB Staff

Office of Legal Services

DHS Office of Regulations

DHS Agency/ Budgets

RTCC

Office of Administrative Law

Dept. of Finance/ Legislature

Public

From Page 3, Step 24

25 Need Additional Public Notice?

Yes

26 Revise & Prepare FSR & UID

26a Review package

27 Package approved?

No

Package must be approved by RHB mngmnt then is forwarded to Division Chief for approval and signature. The review and revision process may go through a number of iterations before the package is approved.

Yes

26b Review package

28 Package approved?

No

Procedural Review

Go to Page 3, Step 23

25a Additional 15 day public comment period. OR collects comments

25b 15 day comment period

Only occurs if text is substantially modified & sufficiently related to text of reg as originally proposed. Substantial modifications not sufficiently related require a new 45 day comment period.

Yes

29 Review for APA compliance.

There may be new questions that were not previously asked.

30 Package approved?

No

30a Determine course of action

Yes

31 Filed with Sec State

This must be accomplished in 1 year from the public notice date or a new public notice must be issued and the process starts over.

30b OAL letter received and filed in rulemaking file

If NRC regulation, forward copy of final package to them.

Regulatory Process
Detailed Process Notes

These detailed process notes delineate the common path that non-emergency regulations follow. Regulations being promulgated as Emergency regulations follow a shortened path and require a certificate of compliance. Emergency regulations must be necessary for the IMMEDIATE preservation of public peace, health and safety, or the general welfare. The emergency regulations become effective before any public notice and hearing.

Step #	Notes
1	***Provide Subject*** ▪ The public can submit to the state a petition for rulemaking. For RHB's process the public will most often present proposals to the Radiologic Technology Certification Committee (RTCC) if the proposal is related to certification in Radiologic Technology. Also, the Nuclear Medicine Advisory Council works directly with RHB to assist in licensing. ▪ The legislature may pass a law requiring RHB to promulgate regulations. The Department of Finance usually does not provide the subject. ▪ California is an Agreement State under the Atomic Energy Act (AEA). The Nuclear Regulatory Commission (NRC) is the federal agency responsible for ensuring compliance with the AEA. California must maintain an adequate and compatible radiation safety program as compared to the federal program. NRC promulgates regulations and agreement states must adopt compatible regulations following "Adequacy and Compatibility of Agreement State Programs, Handbook 5.9."
2	***Provide Subject*** ▪ The RTCC provides much of the current work on regulations. The RTCC is mandated by law to advise, assist and approve regulations pertaining to certification in Radiologic Technology. Currently, the committee meets 2 times a year.
3	***Provide Subject*** ▪ RHB management and Division management may provide the subject for regulation promulgation. ▪ RHB staff provides comments on needed changes in regulations or may identify a new needed change requiring adoption of regulations. ▪ Office of Legal Services attorney may remind the program that a specific law must be specified in regulation.
4	***Receive Subject*** ▪ Program HP receives subject. Subject may be identified during regulatory process and thus becomes input. ▪ Program HP assigned the subject becomes the author of the package. Assignment given by management, supervisor, lead of program staff, or most often by program staff consensus.
5	***Research Subject and Hold Workshop*** ▪ The author researches current laws, regulations, literature, organizational practices related to subject, contacts regulated community, RHB staff, Management, legal staff, Office of Regulations, NRC, RTCC, etc. ▪ Workshops may be held to gain a consensus from the regulated community. There has been only 1 workshop as this area is new to the regulation program. ▪ Research may result in no action on subject, a future action on subject, or become input into a current package.
5a	***Provide Input*** ▪ All identified players on map may provide input during the research phase of the process. ▪ Due to the nature of regulations, input can come from many sources and is not limited to the areas shown. Those shown sources are common and may provide input at all phases.

Step #	Notes
6	***Create Reference File and Initial Rationale*** ▪ All research material is collected and placed in the reference file and may become part of the Rulemaking File which is the official file of the regulatory process. The reference file is a compilation of all material gathered by the author. Some of the material will be put into the official Rulemaking file. Any material in the Rulemaking file becomes accessible to the public. Material not included in the rulemaking file would be private messages, proprietary material, investigations, etc. ▪ The rationale for the proposed change is developed as a framework to conduct the staff reading.
7	***Draft Proposed Regulation and Initial Statement of Reasons*** ▪ Research and development of the initial statement of reasons will assist in preparation for the staff reading. ▪ Format of regulation must be in regulatory format using underline and strikeout notations. ▪ Prepare draft for staff reading. Preparation may include input from RHB staff, legal, Management, resulting in more research.
8	***Schedule Staff Reading*** ▪ Check with Management Secretaries for available day. ▪ Reserve conference room at appropriate day, time. Conference rooms are RHB Curie Room, EMB conference room, building conference room. ▪ Notify RHB Senior staff that a staff reading is scheduled. Participants must receive proposed regulation text draft at least one week prior to meeting. Participants must read draft prior to meeting. ▪ No formal format for this notice since only 2 staff readings has occurred.
9	***Conduct Staff Reading*** ▪ A staff reading shall be conducted for every proposed regulation unless otherwise directed by Management. There is no set time allotted for this. It has ranged from 4 hours to 3 days. Each reading will depend on the scope and complexity of the proposed regulation change. ▪ Comments must be recorded and dated. ▪ Written comments must be dated and include the name of the commenter. Written comments must be logged and kept in the reference file by the author of the package. ▪ A person is designated as the Reader and another as emcee. Every regulation including the authority and reference note must be read. ▪ Staff Readings serve as a quality control mechanism. It may result in redirection of effort, termination of effort, postponement of effort, or continuation of effort. ▪ Individuals attending should be those from each section that have a broad understanding of regulations related to the subject and can offer input during the reading. This may result in one individual from each unit being designated as the spokesperson for that unit for all proposed regulations pertaining to an area of expertise. Areas of expertise should be NRC, Radioactive Materials (licensing, inspection), Radiologic Technology certification, Machines, Financial processes, MQSA/Mammography, legal, Management.
10	***Revise PR & ISR & Send All RHB & Set Deadline*** ▪ After the staff reading the author revises the proposed regulation and initial statement of reasons. Once the PR and ISR are ready, both items are sent to all RHB staff for review. ▪ A period of time is set for the comment period. 3 to 4 weeks are sufficient to allow staff to comment. This amount of time accounts for vacations and required travel by field inspectors. ▪ County & field offices will be included in the comment period. Email, fax or phone call to the county directors will ensure that the counties are afforded comment opportunity. ▪ All staff comments are directed back to the author of the regulation package.

Step #	Notes
10a	***RHB Staff Comment Period*** ▪ RHB staff provides comments directly to the author of package. ▪ Staff must be aware of the set deadline for comment. ▪ Author of package continues to work on other items needed for the regulation package or on other packages.
11	***Research and Revise Proposed Regulations*** ▪ Author of package receives staff comments, researches and revises proposed regulations to accommodate comments. ▪ Comments not related to working package are maintained in the Defect File. The defect file contains comments from staff, comments from regulation program staff and is placed into the appropriate CCR sections that need changes or improvements. ▪ Author must acknowledge all received comments. Author will provide feedback to any staff member whose comments are incorporated into the regulation. ▪ Step 11b will be skipped if OR is unable to provide an informal review. Step 11a will always occur.
11a	***PR & ISR Reviewed*** ▪ OLS attorney reviews PR & ISR before step 11b. The attorney is onsite at the Sacramento office.
11b	***OR Informal Review*** ▪ Proposed regulation text and draft Initial Statement of Reasons are sent to OR for an informal review. This step is neither regulatory nor required by any policy. It occurs only as a courtesy of OR. This informal review was agreed upon in December 1998. ▪ Provides additional comments that must be addressed resulting in additional research and revision of package. It may even result in termination of effort on the particular subject.
12	***Revise PR & ISR*** ▪ The author of package addresses comments from OR and makes appropriate changes.
13	***RTCC Approval Needed?*** ▪ If the proposed regulation falls within the jurisdiction of the RTCC the proposed regulation must be sent to, reviewed and approved by the RTCC. ▪ The RTCC is established by law and serves to assist, advise, recommend and approve regulations pertaining to certification in radiologic technology. The RTCC currently meets once every six months. ▪ Regulation staff addresses RTCC comments and revises PR accordingly. The author may get input from legal, RHB staff, RHB management, RTCC members, Public, etc.
13a	***Proposed Regulations Approved?*** ▪ RTCC must review and approve regulation as required by law. ▪ Author of package should draft a summary concept of proposed regulations. It should contain moderate detail so when the concept is compared to the proposed regulation text there are no regulatory differences.

Step #	Notes
14	***Revise and Prepare Full Package with Transmittal Memo*** ▪ After addressing comments from RTCC, the author prepares the complete package, which contains: Transmittal Memo (TM), Informative Digest (ID), Statement of Determinations (SD), Fiscal Impact (FI), Initial Statement of Reasons (ISR), Proposed Regulation (PR) text, Plain English Statement (PE) if needed, and Finding of Emergency (FE) if package is an emergency package. The package order is TM, ID, ISR, SD, FI, PR, PE (if needed), FE (if needed), Attachments and supporting documentation, electronic copy. ▪ All parts of the full package must follow APA requirements. OR provides guidance in their instructions dated October 1997 for the preparation of regulation proposals. Additional guidance is in the OAL training material. RP staff have copies of these materials. ▪ The program is able to use a certification support supervisor when time allows to assist with processing. Currently, the office technician position is vacant. ▪ The package is prepared and routed to the required staff and management for review. ▪ The transmittal memo will show who reviews and approves of the package. At the top of the memo, boxes identify the person and include the phone number for that person. The people identified in the boxes are: the author, the Senior HP of the author, the Supervising HP of the Senior HP, legal council, the assistant Branch Chief, the Branch Chief.
14a	***Review Package*** ▪ RHB management (regulation program Senior HP, Supervising HP, Assistant Branch Chief, Branch Chief) review the package. The criteria used includes but is not limited to grammatical errors, unclear or false statements, logical flow of the statement of reasons, etc. ▪ The Division Chief reviews the package after RHB management and attorney have reviewed and approved the package.
14b	***Review Package*** ▪ At the same time RHB management reviews the package the attorney will also review the package for completeness. The OLS attorney is onsite so step 14a and 14b occur in the Sacramento office.
15	***Package Approved*** ▪ The transmittal memo is addressed to the Office of Regulations as being approved by the Division Chief and must be signed by the Division Chief. ▪ The regulation package is sent to OR by the regulation program and must contain five copies of complete package except only 2 copies of the attachments and supporting documentation and 1 electronic copy. ▪ All copies hand carried to OR by regulation staff member or the certification support supervisor.
16	***Formally Review Regulation Package*** ▪ OR receives package for formal review. ▪ OR directs a copy to the DHS Budget Analyst and to OLS.
17	***Package Approved*** ▪ The package is returned to RHB with comments. 100% of package are returned with comments. ▪ OLS and Budgets must also approve the package. Budget section works directly with RHB regulation program to evaluate fiscal impact issues and completes form STD-399, Fiscal Impact Statement. STD-399 must be completed and signed by Budget director for each regulation package. OLS works directly with OR on identified legal problems. OR may need to contact program or the onsite attorney.

Step #	Notes
17a	***Revise to Address Comments and Prepare New Transmittal Memo*** ▪ The package is revised to address comments from OR. ▪ A new transmittal memo is written stating that the agency has addressed the comments from OR. ▪ Packages that fall under RTCC jurisdiction go to step 12. ▪ Packages that are non-RTCC go to step 14.
17b	***Package Approved?*** ▪ If the package affects state funds the Department of Finance must approve the proposed regulation. ▪ If it is approved the required form is sent back to office of regulations in step 17.
18	***Coordinate Director Approval, Prepares Public Notice & Forwards to Office of Administrative Law (OAL)*** ▪ Once the package receives approval by OR, Budgets, and OLS, OR will work with DHS agency to gain director approval. If the Director does not approve the proposed regulation RHB management must determine course of action. ▪ OR prepares the Public Notice that will be published by OAL in the California Regulatory Notice Register (also called the "Z-register"). The Notice is forwarded to OAL. ▪ OAL reviews the public notice. ▪ Regulation Program sends a copy of the proposed regulations if evaluation is needed from NRC regarding compatibility. This submission is to follow the NRC guideline "Review of State Regulations - SA-201."
19	***Public Notice Approved?*** ▪ OAL has 3 days in which to review and approve the notice. If corrections are needed OAL works with OR to make appropriate changes. Once approved it is published in the California Regulatory Notice Register.
20	***Publish Public Notice*** ▪ The Public Notice is published in the California Regulatory Notice Register, which is issued every Friday. ▪ The publication date starts the 45-day public comment period. ▪ The publication date also starts the one-year drop-dead date in which the regulations must be filed with the Secretary of State, if approved. ▪ OR sends a copy of the notice to individuals who have requested to be notified of proposed regulations. The list of individuals is provided to OR by the state agency proposing the changes.
21	***Public Comment Period*** ▪ The public has 45 days to provide comments. ▪ A public hearing must be held if requested no later than 15 days prior to the close of the written comment period.
22	***Collect Comments during Public Comment Period*** ▪ OR is the contact for the public. ▪ OR collects the public comments.
23	***Senior HP Receive Comments and Gives to Author of Package*** ▪ OR sends all received comments back to RHB.
24	***Compile and Address Public Comments*** ▪ All comments received during the public comment period must be addressed. Received comments do not necessarily change proposed regulation but must be considered and answered appropriately. ▪ The comments should be compiled in an orderly manner. OAL and OR may provide assistance during this step. ▪ The author of package may need to contact the commenter.

Step #	Notes
25	***Need Additional Public Comment?*** ▪ If the comments indicate a change to the regulation is needed, and the changes are substantial modifications sufficiently related to the text or regulation as originally proposed the Administrative Procedure Act (APA) requires an additional public comment period. This is a period of 15-days. ▪ If the changes are substantial modifications that are NOT sufficiently related to the original proposal a new 45-day comment period is required. ▪ Go to step 26 if no additional 15 day comment period is needed.
25a	***Additional 15-day public Comment Period*** ▪ In the event changes are made that are substantial an additional 15 day Public comment period must be made. ▪ OR collects the comments and forwards them to RHB. ▪ The process can be reiterated as necessary. CAVEAT: the 1-year drop-dead clock is still ticking. ▪ Go to step 25b.
25b	***15-day Public Comment Period*** ▪ The comment period is limited to those who commented during the 45-day period.
26	***Revise and Prepare Final Statement of Reasons (FSR) & Updated Informative Digest (UID)*** ▪ Address comments in the Final Statement of Reasons (FSR) and prepare Updated Informative Digest (UID). The FSR must address all comments sufficiently. Legal staff will participate in this.
26a	***Review Package*** ▪ RHB management reviews the final package.
26b	***Review Package*** ▪ OLS attorney reviews the final package.
27	***Package Approved?*** ▪ If RHB management and the attorney approve package it is sent to the Division Chief for approval. If the final package is approved it is sent to OR for Department review and approval (step 28). ▪ If the package is not approved it is sent back to regulation staff (step 26) and revised to meet comments. This loop will occur until approved or the one-year drop-dead date is exceeded or Management/Division/Department terminates effort. ▪ If the package is officially denied due to not meeting the APA or exceeds the 1-year drop-dead period, the denial is published in the California Regulatory Register Notice with the same published denial being sent to RHB. ▪ There is an informal process, which is usually used to correct issues OAL has. This informal process usually results in an approved package.
28	***Review and Package Approved?*** ▪ The package is reviewed by OR and if approved is forwarded to OAL for APA review. ▪ If package is disapproved go to step 26.
29	***Review for APA Compliance*** ▪ OAL reviews package to ensure that all legal requirements have been met. OAL does not weigh the evidence in the package to determine whether the rulemaking agency made the "best" decision. OAL determines whether the record contains substantial evidence to support the regulation adopted by the agency and meets all requirements.
30	***Package Approved?*** ▪ If the package is approved it is filed with the Secretary of State (step 31).
30a	***Determine Course of Action*** ▪ If package is denied RHB must determine course of action.

Step #	Notes
30b	***OAL Letter Received and Filed in Rulemaking File*** ▪ OAL sends a letter of notification that the proposed regulation is approved and is filed with the Secretary of State. The letter, all comments and correspondence received during process are maintained in the rulemaking file as required by law. Once a package is effective the rulemaking file must be kept indefinitely and nothing can be removed or added to it. It is the official file of the regulatory process. ▪ A copy of the final adopted regulations are sent to NRC if evaluation is needed for compatibility.
31	***Filed with Secretary of State*** ▪ Once approved by OAL the regulation proposal is filed with the secretary of state. The proposed regulation becomes effective 30 days after the filing. Or, if the Department specified an effective date, that specified date will be the effective date. This filing must be made no later than one year from the published public notice date.

Regulatory Process

Process Overview Document

Each regulation package is unique. Identified issues may be narrow in scope or extremely broad and complex. Each package will have a large number of participants whose role may change at any time. An effort at regulation promulgation may not always result in the goal. This process overview is not inclusive of all aspects of regulation promulgation but is intended to provide a broad understanding of each component.

Ref. #	Component	Information
1	**Process Name**	▪ Regulatory Process
2	**Process Goal**	▪ To amend a Regulation ▪ To adopt a Regulation ▪ To repeal a Regulation ▪ To make changes with no regulatory effect. (e.g., typo, repealed sections, sunset regulatory language, restructure section numbers)
3	**Trigger(s)**	▪ RTCC ▪ NRC ▪ Public ▪ Legislative mandate ▪ Law ▪ Public health and safety issue ▪ Department Recommendation ▪ RHB staff or management ▪ FDA, EPA ▪ Nuclear Medicine Advisory Council ▪ Regulation Package split
4	**Input(s)**	▪ RTCC ▪ NRC ▪ Public ▪ Legislative mandate ▪ Law ▪ Public health and safety issue ▪ Department Recommendation ▪ RHB staff or management ▪ FDA, EPA ▪ Nuclear Medicine Advisory Council ▪ Regulation Package split

Ref. #	Component	Information
5	**Product(s)** or **Output(s)**	▪ Amended Regulation ▪ Adopted Regulation ▪ Repealed Regulation ▪ Corrected - Restructured Regulation ▪ Rulemaking File NOTE: There are 3 paths for regulation promulgations: Non-emergency, Emergency, Section 100. Each path has a specific legal time line for review and approval. See Notes. The Branch must maintain the rulemaking file indefinitely.
6	**Process Participants** and **Primary Responsibilities** within this process	▪ RTCC - assist, advise, recommend and approve regulations pertaining to certification in radiologic technology. ▪ NRC - assist in developing regulations compatible with federal requirements, certain radioactive material only. Provide comments during process ▪ Federal agencies - provide input at all stages of process ▪ Public – professionals, regulated community, general public: provide input as subject matter experts or concerns during development and Public Hearing Notice period ▪ Legislature – provide input in the form of mandates, laws, and reports to legislature ▪ Office of Legal Services - assist and advise, provide recommendations during development and provide legal over-site to program. RHB has one lawyer dedicated to work with regulation program ▪ DHS and HHW - input from division chief and any agency policy decisions usually during development or during OR review and prior to OAL review ▪ State & Local agencies - input during development or during Public Hearing Notice period on regulations affecting that agency (e.g. Cal-OSHA, Cal-EPA, DTSC) ▪ RHB staff and management - input as subject matter experts, management must approve regulation package before package is put into the Office of Regulation (OR) approval process ▪ Office of Regulations – provide Department over-site and review of package before package put into legal process with Office of Administrative Law (OAL) ▪ Office of Administrative Law - provide orderly review of adopted regulations by law. Administer the APA requirements
7	**Key Customers**	▪ Citizens of California ▪ Regulated community - all radiation users. ▪ RHB ▪ State and Federal Agencies

Ref. #	Component	Information
8	**Primary Regulations or Policies** (for this process only)	▪ Administrative Procedure Act - Major Regulation ▪ All California laws and regulations applicable to subject of regulation under development. ▪ State Administrative Manual ▪ Health Administrative Manual ▪ Federal Regulations and Laws applicable to subject of regulation under development. ▪ Department policies. ▪ Branch Policies
9	**Performance / Baseline Information** (e.g. volumes, processing times, cycle times, backlogs, fees collected, and other relevant data)	▪ The regulation program is a new effort. Performance criteria are being discussed and once approved, will be collected. ▪ NRC compatible regulations must be adopted within 3 years of NRC effective date ▪ Each part of the legal review is specified as to the time allowed in each part. There is a one-year drop-dead date ▪ Processing times vary for each package. No formal baseline information exists except for the date a package is sent to OR or OAL and is contained in the rulemaking files and status file ▪ Backlogs change constantly due to combined packages, split packages, etc.
10	**Information Systems used**	▪ MS-Word : many of the programs now on the LAN ▪ Internet, Intranet ▪ MS-Access ▪ MS-Excel ▪ Files and textbooks available in RHB office ▪ Federal regulations kept in binders ▪ Federal Register ▪ State Program letters from NRC ▪ Personal copies of laws and regulations ▪ Libraries - State, Universities, Counties, Local ▪ OAL Training material ▪ OR Training material ▪ RP staff training needs not fully identified

DHCS/OOR
Regulation Process Milestones
(Non-Emergency Packages)

	Estimated Time Frame	Activity
1	30 days *	OOR review of the regulation package.
2	30 days *	OLS review of the regulation package.
3	30 days *	Program revisions based on OOR and OLS reviews.
4	10 days *	Program and OOR finalize regulation package. (Reconciliation of remaining issues)
5	30 days *	CDHS Fiscal Forecasting Review of the package.
6	22 days	Director's Office review of the package.
7	1 day	Package submitted to HHSA.
8	Unknown	HHSA review of the package.
9	Unknown	DOF review of the package. (If applicable)
10	14 days	OOR prepares public notice package for final Director's Signature.
11	30 days	Routing of the Public Notice Package for the Director's Signature, via OLS, for submittal to OAL.
12	3 days	OAL's review of the public notice.
13	30 days	Duplication and Mailing.
14	45 days	Public Comment Period.
15	30 days *	Program reviews and evaluates public comments and determines if any changes should be made to the regulations as noticed.
16	14 days	Program makes any required changes to the regulations.
17	20 days *	OOR review of the proposed changes.
18	20 days *	OLS review of the proposed changes.
19	7 days	Program and OOR finalize proposed changes. (Reconciliation of remaining issues)
20	14 days	OOR prepares a 15-day notice and routes for the Director's signature, via OLS.
21	30 days	Duplication and Mailing.
22	15 days	Regulation text revisions are made available for public comment. (15-Day Availability)
23	Repeat steps 15-22 above	If it is determined that a 2nd Post Hearing Change 15-Day Availability Period is required.
24	30 days *	Preparation by Program of the Updated Informative Digest, All Responses to Comments, Regulation Text, and FSOR.
25	20 days *	OOR review of the Updated Informative Digest, All Responses to Comments, Regulation Text, and FSOR.
26	20 days *	OLS review the Updated Informative Digest, All Responses to Comments, Regulation Text, and FSOR.
27	30 days	OOR prepares package for filing with OAL and routes package for Director's signature.
28	7 days	Adoption of Filing Order by Director and Filing with OAL.

DHCS/OOR
Regulation Process Milestones
(Non-Emergency Packages)

29	45 days	OAL's review of the package and if approved filing with the SOS.
30	30 days	Regulations become effective 30 days after filing with SOS or on an alternative designated date.

Key:
CDHS – California Department of Health Services
DOF – Department of Finance
FSOR – Final Statement of Reasons
HHSA – Health and Human Services Agency
OAL – Office of Administrative Law
OLS – Office of Legal Services
OOR – Office of Regulations
SOS – Secretary of State

** Actual review timeframes will vary depending on the size and complexity of each regulation package, staff workload and the order of receipt of the regulation package/revisions.*

** For planning purposes, excluding steps 8, 9, and 23, the estimated length of time required for the non-emergency regulation process is 607 days.*

DHCS/OOR
Regulation Process Milestones
(Emergency Packages)

	Estimated Time Frame	Activity
1	30 days *	OOR review of the regulation package.
2	30 days *	OLS review of the regulation package.
3	30 days *	Program revisions based on OOR and OLS reviews.
4	10 days *	Program and OOR finalize regulation package. (Reconciliation of remaining issues)
5	30 days *	CDHS Fiscal Forecasting Review of the package.
6	22 days	Director's Office review of the package.
7	1 day	Package submitted to HHSA.
8	Unknown	HHSA review of the package.
9	Unknown	DOF review of the package. (If applicable)
10	20 days	OOR prepares for the Director's Signature: 1) Notice of Intent, for release prior to OAL submission. *(The notice of intent package includes: Public Notice, Regulation Text & FOE)* (NOTE: Such a notice is not required if the emergency situation clearly poses such an immediate, serious harm that delaying action to allow for public comment would be inconsistent with public interest *(GC Section 11346.1(a)(3)*) 2) Public Notice Package for submission to OAL *(The public notice package includes: Public Notice, Regulation Text, ISOR/SOD, & FOE)* OOR also prepares to submit to OAL: 3) Emergency Filing Order Package that will be submitted along with the Public Notice Package indicated under 2).
11	30 days	OOR routes the Public Notice(s) & Package for the Director's Signature, via OLS.
12	30 days	Duplication and Mailing of the Notice of Intent, for release prior to OAL submission. (if applicable)
13	8 days	Public Notice Period (5 working days)
14	1 day	OOR files the Public Notice Package & Emergency Filing Order with OAL.
15	10 days	OAL review of the public notice/approval of the filing order and filing with the SOS on approved date or designated later date.
16	30 days	Duplication and Mailing of Public Notice Package that was submitted to OAL.
17	45 days	Public Comment Period.
18	30 days *	Program reviews and evaluates public comments and determines if any changes should be made to the regulations as noticed.

In the event of Post-Hearing Changes a re-adoption may be considered near the end of the 180 days.
(2 re-adoptions may be requested, each not to exceed 90 days)

DHCS/OOR
Regulation Process Milestones
(Emergency Packages)

19	14 days	Program makes any required changes to the regulations.
20	20 days *	OOR review of the proposed changes.
21	20 days *	OLS review of the proposed changes.
22	7 days	Program and OOR finalize proposed changes. (Reconciliation of remaining issues)
23	14 days	OOR prepares a 15-day notice and routes for the Director's signature, via OLS.
24	30 days	Duplication and Mailing.
25	15 days	Regulation text revisions are made available for public comment. (15-Day Availability)
26	Repeat steps 18-25 above	If it is determined that a 2nd Post Hearing Change 15-Day Availability Period is required.
27	30 days *	Preparation by Program of the Updated Informative Digest, All Responses to Comments, Regulation Text, and FSOR.
28	20 days *	OOR review of the Updated Informative Digest, All Responses to Comments, Regulation Text, and FSOR.
29	20 days *	OLS review of the Updated Informative Digest, All Responses to Comments, Regulation Text, and FSOR.
30	30 days	OOR prepares package for filing with OAL and routes package for Director's signature.
31	7 days	Certificate of Compliance (including adoption of any changes following the initial adoption of the ER regulations) signed by the Director and Filed with OAL.
32	45 days	OAL's review and approval of the package (including changes made following the initial adoption of the ER regulations). OAL files with the SOS, making the regulations permanent.

Key:
CDHS – California Department of Health Services
DOF – Department of Finance
FOE – Finding of Emergency
FSOR – Final Statement of Reasons
HHSA – Health and Human Services Agency
ISOR – Initial Statement of Reasons
OAL – Office of Administrative Law
OLS – Office of Legal Services
OOR – Office of Regulations
SOD – Statements of Determination
SOS – Secretary of State

** Actual review timeframes will vary depending on the size and complexity of each regulation package, staff workload and the order of receipt of the regulation package/revisions.*
** For planning purposes, excluding steps 8, 9, and 26, the estimated length of time required for the emergency regulation process is 629 days.*

HOW TO PARTICIPATE IN THE RULEMAKING PROCESS

THE STATUTES, REGULATIONS AND CASE LAW YOU NEED TO MAKE your VOICE HEARD IN THE CALIFORNIA RULEMAKING PROCESS

HOW TO PARTICIPATE IN THE RULEMAKING PROCESS

A CALIFORNIA STATE AGENCY MUST CONSIDER RECOMMENDATIONS AND OBJECTIONS FROM THE PUBLIC BEFORE IT ADOPTS OR CHANGES ANY REGULATION NOT EXPRESSLY EXEMPTED FROM THE CALIFORNIA ADMINISTRATIVE PROCEDURE ACT (APA). A **"REGULATION" IS A POLICY OR PROCEDURE AFFECTING THE PUBLIC OR ANY SEGMENT OF THE PUBLIC THAT IMPLEMENTS, INTERPRETS, OR MAKES SPECIFIC A STATUTE THE STATE AGENCY ENFORCES OR ADMINISTERS.**

THE PROCEDURE FOR RULEMAKING Every department, division, office, officer, bureau, board or commission in the executive branch of California state government must follow the rulemaking procedures in the Administrative Procedure Act (Government Code § 11340 *et seq.*) The Government Code is available at http://www.leginfo.ca.gov/calaw.htm. Rulemaking must also comply with regulations adopted by the Office of Administrative Law (OAL) (California Code of Regulations, Title 1, §§ 1-120; http://ccr.oal.ca.gov/) unless expressly exempted by statute from some or all of these requirements. OAL's publication, *California Rulemaking Law Under the Administrative Procedure Act,* is an annotated compilation of the California statutes and regulations governing rulemaking and is available from OAL for a nominal fee. The checklists used by OAL in its review of regulation filings are available online at http://www.oal.ca.gov/rulemaking.htm.

THE CALIFORNIA CODE OF REGULATIONS Regulations are printed in the California Code of Regulations after they are adopted by the rulemaking agency, approved by OAL and filed with the Secretary of State. You may access regulations in the California Code of Regulations at http://ccr.oal.ca.gov.

PRE-NOTICE INVOLVEMENT An agency may involve the public in workshops or other preliminary activities well before the start of the formal rulemaking process. Government Code section 11346.46 requires an agency proposing to adopt complex proposals or a large number of proposals to involve the public. You can contact the agency and request to be added to their regulations mailing list to ensure you are notified of this opportunity. Also, agency websites often provide information on upcoming rulemaking actions. For websites, go to the State Agency Index under "Quick Hits" at: http://www.ca.gov.

COMMENTING ON THE INITIAL PROPOSAL A 45 day opportunity to submit written, faxed, or e-mail comments on all or any part of a proposed rulemaking action starts when the notice of proposed rulemaking is published in the California Regulatory Notice Register. The Notice Register may be accessed online at http://www.oal.ca.gov/notice.htm. The notice of proposed rulemaking is also mailed to those who have asked to be on the agency's notice mailing list, and is posted on the rulemaking agency's website. The notice tells you how to obtain access to the proposed regulation text and the initial statement of reasons and who to call if you have questions. The notice may also schedule a public hearing at which you may comment on the proposal orally and/or in writing.

COMMENTING ON MODIFICATIONS TO THE INITIAL PROPOSAL You will receive a notice of any 15 day opportunity to comment (1) on proposed modifications or (2) new material relied upon if you commented on the initial proposal or have requested such notice. The rulemaking agency also posts a copy of the notice of opportunity to comment on proposed modifications on its website.

MAKING AN EFFECTIVE COMMENT Effective comments are based on an understanding of the statutes and factual material the agency relies on in proposing the regulation, on an understanding of what the proposed regulation is intended to do, and on an understanding of the standards the regulation must satisfy. The Authority and Reference citations that follow the text of each regulation section identify the statutes on which the section is based. The initial statement of reasons describes the purpose and rationale of each regulation and identifies the factual material upon which the agency relies in proposing it. The response to comments in the final statement of reasons must demonstrate that each relevant, timely comment has been considered.

STANDARDS FOR REGULATIONS A regulation must be easily understandable, have a rationale, and be the least burdensome, effective alternative. A regulation cannot alter, amend, enlarge, or restrict a statute, or be inconsistent or in conflict with a statute.

EMERGENCY REGULATIONS An emergency regulation takes effect immediately, before the regular public opportunity for notice and comment. A state agency may adopt an emergency regulation if it can show that the regulation is necessary for the immediate preservation of public peace, health and safety, or general welfare, or if a statute deems the regulation to be an emergency for purposes of the APA. The public may comment directly to OAL on emergency regulations within 5 days after the regulation is submitted to OAL for review, if OAL has not taken action on the regulations before that time. The state agency may submit a rebuttal to any comments made on an emergency regulation up to eight days after the regulation is submitted to OAL. OAL has up to 10 calendar days to review an emergency regulation. You will find additional information about emergency regulations and how to comment on them at **http://www.oal.ca.gov/emergency.htm**. OAL reviews emergency regulations to determine whether an emergency has been demonstrated, or deemed by statute and whether the regulation satisfies the Authority, Reference, Consistency, Clarity, Nonduplication, and Necessity standards. Once approved, an emergency regulation remains in effect for 120 days, unless the state agency has a special statute allowing more or less time. During the time the emergency is effective, the rulemaking agency must conduct

the regular rulemaking process to permanently adopt the regulation. If, however, the agency is unable to complete the rulemaking process within that time, the agency may request permission from OAL to readopt the emergency regulation for another 120 days.

AN OVERVIEW OF THE RULEMAKING PROCESS Administrative Procedure Act requirements are designed to provide the public with a meaningful opportunity to participate in the adoption of regulations by California state agencies and to ensure the creation of an adequate record for the public and for OAL and judicial review. Every California state agency must satisfy the basic minimum procedural requirements established by the APA for the adoption, amendment or repeal of an administrative regulation unless the agency is expressly exempted by statute. (Graphic on pages 6 and 7 illustrates the rulemaking process.)

A DELEGATION OF RULEMAKING AUTHORITY How can a state agency in the executive branch adopt rules and regulations that have the force of law? The California Constitution separates the powers of the state government into legislative, executive, and judicial powers, and provides that persons charged with the exercise of one power may not exercise either of the others except as permitted by the Constitution. The Constitution also vests the legislative power of the State in the Legislature, but reserves to the people the powers of initiative and referendum.

California courts have long recognized that under the Constitution the Legislature may by statute delegate quasi-legislative powers to a state agency in the executive branch, so long as adequate standards are provided to guide the agency. The adequacy of such a delegation is virtually never an issue in a rulemaking because all state agencies, including OAL, must presume that any California statute, including one delegating rulemaking authority, is constitutional unless an appellate court has made a determination to the contrary. (California Constitution, Article 3, Section 3.5.) Thus every rulemaking action must be based upon a statutory delegation of rulemaking authority from the Legislature to a state agency.

PRELIMINARY ACTIVITIES What does a state agency do once it decides to conduct a rulemaking action? It makes the decisions and develops the documents required to conduct a formal APA rulemaking proceeding. Some agencies involve the public during this stage. Others do not. The APA in Government Code section 11346.45 provides that an agency must engage in pre-notice public discussions regarding complex proposals or large proposals. A decision to engage or not engage in such discussions, however, is not subject to review by OAL or the

courts. The agency develops four documents during the preliminary activity stage, which are needed to initiate the formal rulemaking process: the express terms of the proposed regulation (the proposed text), the initial statement of reasons, the STD 399 Fiscal Impact Statement, and the notice of proposed rulemaking.

SPECIAL CONSIDERATIONS The APA requires a rulemaking agency to make specified determinations and findings with regard to a proposed action.

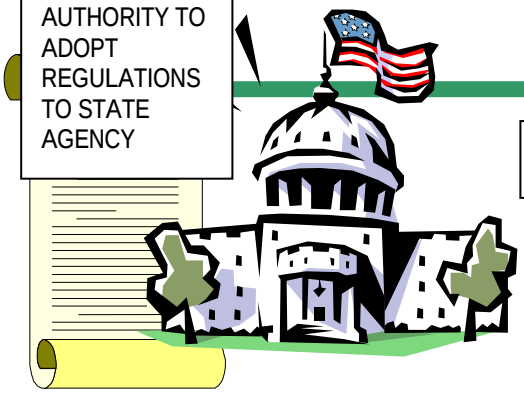
- An agency must find that no alternative would be more effective in carrying out the purpose for which a regulation is proposed or would be as effective as and less burdensome to affected private persons than the adopted regulation.
- A rulemaking agency must determine whether the regulation "may have," or "will not have" a significant, statewide adverse impact directly affecting business. The agency must solicit alternatives if it "may have."
- A rulemaking agency must describe the potential cost impact of a regulation on a representative private person or business, if known.
- A rulemaking agency must assess whether and to what extent the regulation will create or eliminate jobs and businesses. A rulemaking agency must find that any business reporting requirement is necessary for the public health, safety, or welfare.
- A rulemaking agency must consider the substitution of performance standards for prescriptive standards.
- A rulemaking agency must state whether a regulation affects small business.
- A rulemaking agency must state whether a regulation differs from a federal statute or regulation and avoid unnecessary duplication or conflict.
- If a rulemaking agency makes a determination regarding significant effect on housing costs it must include the determination in the notice.

ISSUING THE NOTICE To initiate a rulemaking action, an agency issues a notice of a proposed rulemaking by having the notice published in the California Regulatory Notice Register, by mailing the notice to those persons who have filed a request for notice of regulatory actions, and by posting the notice, text, and statement of reasons on its website, if it has one. Once the notice is issued, the APA rulemaking process is officially under way.

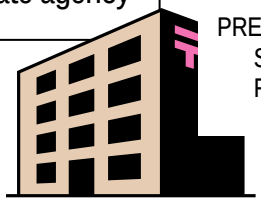
AVAILABILITY OF THE PROPOSED TEXT AND THE INITIAL STATEMENT OF REASONS Agencies that have websites must make notice, the proposed text and the initial statement of reasons available there. The proposed text and the initial statement of reasons are also available on request to the agency contact person identified in the notice.

The Rulemaking Process

LEGISLATURE GRANTS AUTHORITY TO ADOPT REGULATIONS TO STATE AGENCY



State agency



PRELIMINARY ACTIVITIES
Special Considerations
Fiscal Impact

NOTICE OF PROPOSED RULEMAKING

INITIAL STATEMENT OF REASONS

TEXT OF REGULATIONS

RULEMAKING RECORD OPEN

PUBLISHES & ISSUES NOTICE

PUBLIC HEARING

Minimum 45 day public comment period

AGENCY HOLDS PUBLIC HEARING AS SCHEDULED OR BY REQUEST

AGENCY CONSIDERS COMMENTS

CHANGES MADE TO REGULATIONS?

Major Changes: New 45 day notice

substantial & sufficiently related

non-substantial or no changes

15 Day-Comment Period; Agency mails Notice of Proposed Changes

FINAL STATEMENT OF REASONS

SUMMARY & RESPONSE TO COMMENTS:

Changed to accommodate

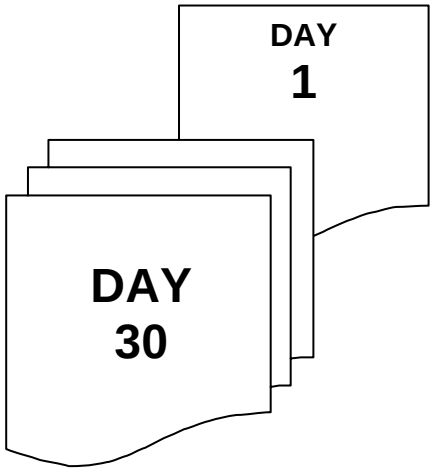
Agency adopts regulation

RULEMAKING RECORD CLOSED

OAL REVIEW

State agency must submit rulemaking record within 1 year of notice publication

OAL has 30 WORKING days to review a regulation



APA STANDARDS:

AUTHORITY
REFERENCE
CONSISTENCY
CLARITY
NON–DUPLICATION
NECESSITY

& PROCEDURAL REQUIREMENTS

DOES THE RULEMAKING SATISFY THE APA?

YES

OAL Files regulation with Secretary of State

USUALLY EFFECTIVE IN 30 DAYS

Regulation printed in California Code of Regulations

NO

OAL returns regulation to agency

Publishes disapproval in Notice Register and California Code of Regulations Decisions

Agency revises text; does 15-day notice; & resubmits to OAL w/in 120 days

NEW PUBLIC NOTICE

OR

APPEALS TO THE GOVERNOR

THE 45 DAY COMMENT PERIOD The APA requires, at minimum, a 45 day opportunity to comment in writing, by fax, or e-mail on the regulation changes as initially proposed by the agency. The notice of proposed rulemaking specifies where the comments must be directed and when this opportunity to comment in writing on the initial proposal closes.

THE PUBLIC HEARING Under the APA, an agency has an option as to whether it wishes to hold a public hearing on a proposed rulemaking action. (An agency's enabling statutes may eliminate this option by requiring a public hearing.) However, if an agency doesn't schedule a public hearing, and any interested person submits a written request for one within 15 days prior to the close of the written comment period, the agency must give notice of, and hold a public hearing. Because of this requirement, a rulemaking agency usually schedules a public hearing unless it is confident that one will not be requested.

CONSIDERATION OF PUBLIC INPUT ON THE INITIAL PROPOSAL The APA requires a rulemaking agency to consider all relevant matter presented to it during a comment period before adopting, amending, or repealing any regulation.

ASSESSING THE NATURE OF MODIFICATIONS TO THE INITIAL PROPOSAL After the initial public comment period, a rulemaking agency will often decide to change its initial proposal either in response to public comments or on its own. The agency must then decide whether a change is: (1) nonsubstantial, (2) substantial and sufficiently related, or (3) substantial and *not* sufficiently related.

MAKING CHANGES AVAILABLE FOR PUBLIC COMMENT The APA provides that a rulemaking agency must make each substantial, sufficiently related change to its initial proposal available for public comment for at least 15 days before adopting such a change. Thus, before a rulemaking agency adopts such a change, it must mail a notice of opportunity to comment on proposed changes along with a copy of the text of the proposed changes to each person who has submitted written comments on the proposal, testified at the public hearing, or asked to receive a notice of proposed modification. The agency must also post the notice on its website. No public hearing is required. The public may comment *on the proposed modifications* in writing. The agency must then consider comments received during the comment period, which are directed at the proposed changes. An agency may conduct more than one 15 day opportunity to comment on a large, complicated, or sensitive rulemaking action before the final version is adopted.

OPPORTUNITY FOR PUBLIC COMMENT BASED UPON NEW MATERIAL RELIED UPON A rulemaking agency must specifically identify in the initial statement of reasons and include in the rulemaking record the material it relies upon in proposing a rulemaking action. If during a rulemaking proceeding an agency decides to rely on material that it did not identify in the initial statement of reasons or otherwise identify or make available for public review prior to the close of the public comment period, the agency must make the document available for comment for 15 days.

SUMMARY AND RESPONSE TO COMMENTS A rulemaking agency must summarize and respond on the record to timely comments that are directed at the rulemaking proposal or at the procedures followed. The summary and response to comment demonstrates that the agency has understood and considered all relevant material presented to it before adopting, amending, or repealing a regulation. An agency may respond to a comment in one of two ways. The agency must either (1) explain how it has amended the proposal to accommodate the comment, or (2) explain the reasons for making no change to the proposal. An agency's summary and response to comments is included as part of the final statement of reasons.

SUBMISSION OF A RULEMAKING ACTION TO OAL FOR REVIEW A rulemaking agency must transmit a rulemaking action to OAL for review within a year from the date that the notice of proposed rulemaking action was published in the California Regulatory Notice Register. OAL then has 30 working days in which to review the rulemaking record to determine whether it demonstrates that the rulemaking agency satisfied the procedural requirements of the APA, and to review regulations for compliance with the six standards: Authority, Reference, Consistency, Clarity, Nonduplication, and Necessity. OAL may not substitute its judgment for that of the rulemaking agency with regard to the substantive content of the regulations.

WHAT MUST BE ADOPTED PURSUANT TO THE APA?

Not every statute requires the adoption of an implementing regulation. In this regard, it is useful to think about three types of statutory provisions:

self-executing--wholly-enabling--susceptible to interpretation.

A self-executing provision is so specific that no implementing or interpreting regulation is necessary to give it effect. An example is a statutory provision that provides: "The annual licensing fee is $500."

In contrast, a wholly-enabling statutory provision is one that has no legal effect without the enactment of a regulation. An example is a statute that provides: "The department may set an annual licensing fee up to $500." This type of statute cannot be legally enforced without a regulation setting the fee.

The third type, a statutory provision that is susceptible to interpretation, may be enforced without a regulation, but may need a regulation for its efficient enforcement. An example is a statute that provides: "There shall be adequate space between hospital beds." Conceptually, this statute could be enforced on a case-by-case basis, but such enforcement would probably present significant difficulties. *(It does not violate the APA to enforce or administer a statute on a case-by-case basis so long as no rule or standard of general application is used that should have been adopted pursuant to the APA.)*

Every "regulation" is subject to the rulemaking procedures of the APA unless expressly exempted by statute.
Government Code Section 11346

IT'S MANDATORY Compliance with the rulemaking requirements of the Administrative Procedure Act is mandatory. (***Armistead v. State Personnel Board.***) All regulations are subject to the APA, unless expressly exempted by statute. (***Engelmann v. State Board of Education.)*** Any doubt as to the applicability of the APA should be resolved in favor of the APA. (***Grier v. Kizer***.) If a rule looks like a regulation, reads like a regulation, and acts like a regulation, it will be treated by the courts as a regulation whether or not the issuing agency so labeled it. (***SWRCB v. OAL***.)

"Regulation" means <u>every</u> rule, regulation, order, or standard of general application or the amendment, supplement, or revision of <u>any</u> rule, regulation, order or standard adopted by <u>any</u> state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure.
Government Code section 11342.600

A GENERAL RULE A standard or procedure of general application (general rule) is a standard or procedure that applies to an open class. (***Roth v. Department of Veterans Affairs***.) An open class is one whose membership could change. *This broad definition includes many classes of rules that are exempt from notice and comment under the federal Administrative Procedure Act.*

THE PROHIBITION The APA specifically prohibits any state agency from making any use of a state agency rule which is a "regulation" as defined in Government Code section 11342.600, that should have, but has not been adopted pursuant to the APA (unless expressly exempted by statute). Such a rule is called an "underground regulation" and its efficacy may be challenged to OAL or to a court.

No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, which is a "regulation" under the APA unless it has been adopted as a regulation and filed with the Secretary of State pursuant to the APA. Government Code section 11340.5(a)

ARMISTEAD V. STATE PERSONNEL BOARD

In 1978, the California Supreme Court made it clear that compliance with the rulemaking requirements of the Administrative Procedure Act is mandatory. (***Armistead v. State Personnel Board.***) In doing so, the court quoted a 1955 legislative report finding that noncompliance with APA rulemaking requirements was common.

> "The committee is compelled to report to the Legislature that it has found many agencies which avoid the mandatory requirements of the Administrative Procedure Act of public notice, opportunity to be heard by the public, filing with the Secretary of State, and publication in the Administrative Code.
>
> "The committee has found that some agencies did not follow the act's requirements because they were not aware of them; some agencies do not follow the act's requirements because they believe they are exempt; at least one agency did not follow the act because it was too busy; some agencies feel the act's requirements prevent them from administering the laws required to be administered by them; and many agencies . . . believe the function being performed was not in the realm of quasi-legislative powers.
>
> "The manner of avoidance takes many forms, depending on the size of the agency and the type of law being administered, but they can all be briefly described as 'house rules' of the agency.
>
> "They consist of rules of the agency, denominated variedly as 'policies,' 'interpretations,' 'instructions,' 'guides,' 'standards,' or the like, and are contained in internal organs of the agency such as

manuals, memoranda, bulletins, or are directed to the public in the form of circulars or bulletins." [First Report of the Senate Interim Committee on Administrative Regulations (1955) as cited in ***Armistead***, p. 205.]

HOW TO DETERMINE WHETHER AGENCY'S POLICY OR PROCEDURE SHOULD BE ADOPTED PURSUANT TO THE APA Preliminarily determine whether the particular policy or procedure is already set out in an applicable statute or duly adopted regulation. (Generally, duly adopted regulations are printed in the California Code of Regulations.) The adoption of a policy or procedure as a "regulation" pursuant to the APA is not required if you find the specific policy or procedure in an applicable statute or duly adopted regulation.

If you determine that the policy or procedure (i.e., rule) is not set out in an applicable statute or duly adopted regulation, use the following three-step analysis to determine whether the policy or procedure must be adopted as a regulation pursuant to the requirements and procedures of the APA:

First, is the policy or procedure either:

- a rule or standard of general application, *or*
- a modification or supplement to such a rule?

Second, has the policy or procedure been adopted by the agency to either:

- implement, interpret, or make specific the law enforced or administered by the agency, *or*
- govern the agency's procedure?

Third, has the policy or procedure been expressly exempted by statute from the requirement that it be adopted as a "regulation" pursuant to the APA?

If the policy or procedure satisfies steps one and two, then it is a "regulation" as defined in the APA and must be adopted pursuant to the APA unless it falls within an express statutory exemption from the requirements of the APA. Generally, all "regulations" issued by state agencies are required to be adopted pursuant to the APA, unless *expressly* exempted by statute. (Government Code section 11346.) If

the policy or procedure does not fall within an express statutory exemption, then it is subject to the rulemaking requirements of the APA.

EXPRESS STATUTORY EXEMPTIONS ARE FOUND IN THE APA AND IN OTHER STATUTES. THE FOLLOWING ARE SOME OF THE EXPRESS EXEMPTIONS SET OUT IN THE APA.

- **INTERNAL MANAGEMENT:** "A regulation that relates only to the internal management of the state agency." (Government Code Section 11340.9(d).)

  The internal management exception to the APA is narrow. A regulation is exempt as internal management if it:

  (1) directly affects only the employees of the issuing agency, and

  (2) does not address a matter of serious consequence involving an important public interest. (***Armistead, Stoneham, Poschman,*** and ***Grier***.)

- **FORMS:** "A form prescribed by a state agency or any instructions relating to the use of the form, but this provision is not a limitation on any requirement that a regulation be adopted pursuant to this chapter when one is needed to implement the law under which the form is issued." (Government Code Section 11340.9(c).)

  This legislative language creates a limited statutory exemption relating to forms. A regulation is *not* needed if the form's contents consist only of existing, specific legal requirements.

  By contrast, if an agency *adds any language which satisfies the definition of "regulation" to the existing legal requirements*, then, under Government Code section 11340.9(c), a formal regulation is "needed to implement the law under which the form is issued." Section 11340.9(c) cannot be interpreted as permitting state agencies to avoid mandatory APA rulemaking requirements by simply typing regulatory language into a form because this interpretation would allow state agencies to ignore the APA at will.

- **AUDIT GUIDELINES:** "A regulation that establishes criteria or guidelines to be used by the staff of an agency in performing an audit, investigation, examination, or inspection, settling a commercial dispute, negotiating a commercial arrangement, or in the defense, prosecution, or settlement of a

case, if disclosure of the criteria or guidelines would do any of the following:

"(1) Enable a law violator to avoid detection.

"(2) Facilitate disregard of requirements imposed by law.

"(3) Give clearly improper advantage to a person who is in an adverse position to the state." (Government Code Section 11340.9(e).)

- **ONLY LEGALLY TENABLE INTERPRETATION:** "A regulation that embodies the only legally tenable interpretation of a provision of law." (Government Code Section 11340.9(f).)

- **RATE, PRICE, TARIFF:** "A regulation that establishes or fixes rates, prices, or tariffs." (Government Code Section 11340.9(g).)

- **LEGAL RULING OF TAX COUNSEL:** "A legal ruling of counsel issued by the Franchise Tax Board or State Board of Equalization." (Government Code Section 11340.9(b).)

- **PRECEDENT DECISION:** A quasi-judicial decision by a state agency that is designated pursuant to Government Code Section 11425.60 as a precedent decision is expressly exempt from being adopted as a "regulation" pursuant to the APA.

AUTHORITY-REFERENCE-CONSISTENCY CLARITY-NONDUPLICATION-NECESSITY

OAL REVIEW FOR COMPLIANCE WITH THE AUTHORITY AND REFERENCE STANDARDS

Each regulation must satisfy the Authority and Reference standards. Complying with the Authority and Reference standards involves a rulemaking agency in two activities: picking appropriate Authority and Reference citations for the note that follows each regulation section to be printed in the California Code of Regulations, and adopting a regulation that is within the scope of the rulemaking power conferred on the agency.

"Authority" means the provision of law which permits or obligates the agency to adopt, amend, or repeal a regulation. Government Code Section 11349(b).

"Reference" means the statute, court decision, or other provision of law which the agency implements, interprets, or makes specific by adopting, amending, or repealing a regulation. Government Code Section 11349(e).

Each regulation section printed in the California Code of Regulations must have a citation to the specific statutory authority under which it was enacted and a citation to the specific statute or other provision of law that the regulation is implementing, interpreting, or making specific. As an example the Authority and Reference Citations for Section 55 of Title 1 of the California Code of Regulations reads as follows: "Authority cited: Sections 11342.4 and 11349.1, Government Code. Reference: Sections 11346.1, 11349.1, 11349.3 and 11349.6, Government Code."

The statutes and other provisions of law cited in Authority and Reference notes are the agency's interpretation of its power to adopt a particular regulation. A rulemaking agency initially selects Authority and Reference citations when it is drafting the proposed regulation text and may revise and refine the citations during

the course of a rulemaking proceeding. The goal is to have accurate, precise, and complete Authority and Reference citations printed in the California Code of Regulations with each regulation.

EXPRESS AND IMPLIED RULEMAKING AUTHORITY A statutory delegation of rulemaking authority may be either express or implied. In an express delegation, the statute expressly states that the state agency may or shall "adopt rules and regulations necessary to carry out this chapter" or some variation on that phrase. Thus, an express delegation *expressly* specifies that regulations shall or may be adopted by the agency.

In contrast, in an implied delegation of rulemaking authority, the applicable statutes do not expressly state that the agency may or shall adopt rules or regulations. Instead, a statute expressly gives a duty or power to a specified state agency, but makes *no* express mention of the authority to adopt rules or regulations. In similar circumstances, courts tell us that agencies which have expressly been given a duty or power by statute have implicitly been delegated the authority to adopt those rules and regulations necessary for the due and efficient exercise of a duty or power expressly granted.

OAL REVIEW FOR AUTHORITY OAL reviews regulations to ensure that they are authorized under controlling statutes. The statutes (and other provisions of law) the agency cites as Authority and Reference identify the sources of the rulemaking power that the agency is drawing on in promulgating a particular regulation. A regulation that is not within the scope of an agency's express or implied rulemaking authority is void and cannot become effective.

Each regulation adopted, to be effective, shall be *within the scope of authority conferred* and in accordance with standards prescribed by other provisions of law.
Government Code Section 11342.1.

In determining whether a rulemaking agency is empowered to adopt a particular regulation, OAL applies the same analytical approach employed by the California Supreme Court and the California Court of Appeal, as evidenced in published opinions of those courts.

JUDICIAL REVIEW OF AUTHORITY TO ADOPT A PARTICULAR REGULATION

When reviewing a quasi-legislative regulation, courts consider whether the regulation is within the scope of the authority conferred, essentially a question of the validity of an agency's statutory interpretation. The courts must determine whether the rulemaking agency has exercised its authority within the bounds established by statute.

Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute. Government Code Section 11342.2.

The courts apply the following principle to determine whether a rulemaking agency has exercised its authority within the bounds established by statute.

An administrative regulation may not alter or amend a statute or enlarge or impair its scope. Such a regulation is void and must be struck down by a court.

In deciding whether a regulation alters, amends, enlarges, or restricts a statute, or merely implements, interprets, makes specific, or otherwise gives effect to a statute often a court must interpret the meaning of the statute. In so doing, courts apply principles of statutory interpretation developed primarily in case law. It examines the language of the statute, and may consider appropriate legislative history materials to ascertain the will of the Legislature so as to effectuate the purpose of the statute. In making this determination, a court may consider, but is not bound by the rulemaking agency's interpretation of the statute at issue. As the California Supreme Court explained in *Yamaha v State Board of Equalization*, "Whether judicial deference to an agency's interpretation is appropriate and, if so, its extent-the 'weight' it should be given is ... fundamentally situational." The court identified factors to be considered relating to (1) the possible interpretive advantage of the agency and (2) to the likelihood that the agency is correct and suggested the following. "The deference due an agency interpretation ... 'will depend *upon the*

thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.'"

OAL REVIEW FOR COMPLIANCE WITH THE CONSISTENCY STANDARD

Each regulation must satisfy the Consistency standard. In reviewing for compliance with the Consistency standard, OAL uses the same analytical approach used in judicial review of a regulation. This approach includes the principles discussed above regarding deference to an agency's interpretation of a statute.

> **"Consistency" means being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law. Government Code, Section 11349(d).**

Commenters on proposed regulations often comment that a proposed regulation is inconsistent with a statute because it requires certain tasks not specifically set out in statute. This situation does not present a Consistency problem so long as the tasks specified in the regulation are reasonably designed to aid a statutory objective, do not conflict with or contradict (or alter, amend, enlarge or restrict) any statutory provision.

In other words, no conflict is presented if the statute says "Thou shall do A" and the regulation says "Thou shall do B," if one can do both A and B, and B is reasonably necessary to effectuate the purpose of A, and does not alter, amend, enlarge, or restrict A. In contrast, a conflict is presented if the statute says "Thou shall do A" and the regulation says "Thou shall not do A."

OAL REVIEW FOR COMPLIANCE WITH THE CLARITY STANDARD

Each regulation must satisfy the Clarity standard. Regulations are frequently unclear and unnecessarily complex, even when the technical nature of the subject matter is taken into account. They are often confusing to persons who must comply with them. The performance goal for drafting a regulation is the following. A rulemaking agency must draft regulation text in plain, straightforward language avoiding technical terms as much as possible using

coherent and easily readable language. The measure of compliance with the performance goal is the Clarity standard. OAL has a duty to ensure that each regulation can be easily understood.

Clarity means written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them. Government Code Sec. 11349(c).

Persons presumed to be "directly affected" by a regulation are those who: (a) must comply with the regulation; or (b) must enforce the regulation; or (c) derive a benefit from the enforcement of the regulation that is not common to the public in general; or (d) incur from the enforcement of the regulation a detriment that is not common to the public in general. California Code of Regulations, Title 1, Sec. 16(b).

Situations in which OAL may presume a regulation is unclear.

1. The regulation has more than one meaning.

2. The language of the regulation conflicts with the description of its effect.

3. The regulation uses an undefined term which does not have a meaning generally familiar to those who are "directly affected."

4. The regulation uses language incorrectly, including incorrect spelling, grammar, or punctuation.

5. The regulation presents information in a format not readily understandable.

6. The regulation does not use citations which clearly identify published material cited in the regulation.

The following regulation drafting tips are drawn from Drafting Legislation and Rules in Plain English, by Robert J. Martineau, (West, 1991) pp 65-105.

1. Use only necessary words.

2. Use common words.

3. Avoid lawyerisms.

4. Be consistent.

5. Use short sentences.

6. Arrange words properly.

7. Tabulate to simplify.

9. Look for omissions and ambiguities.

10. Think through common application situations.

OAL REVIEW FOR COMPLIANCE WITH THE NONDUPLICATION STANDARD

Nonduplication means a regulation does not serve the same purpose as a state or federal statute or another regulation.
Government Code Section 11349(f)

Each regulation must satisfy the Nonduplication standard. A regulation that repeats or rephrases a statute or regulation "serves the same purpose" as that statute or regulation. Any overlapped or duplicated statute or regulation must be identified and the overlap or duplication must be justified. Citing the overlapped or duplicated statute or regulation in the authority or reference note satisfies the identification requirement. Overlap or duplication is justified if information in the rulemaking record establishes that the overlap or duplication is necessary to satisfy the Clarity standard.

OAL REVIEW FOR COMPLIANCE WITH THE NECESSITY STANDARD

An agency conducting a rulemaking action under the APA must compile a complete record of a rulemaking proceeding including all of the evidence and other material upon which a regulation is based.

In the record of the rulemaking proceeding (record), the agency must state the specific purpose of each regulatory provision and explain why the provision is reasonably necessary to accomplish that purpose. It must also identify and include in the record any materials relied upon in proposing the provision and any other information, statement, report, or data the agency is required by law to consider or prepare in connection with the rulemaking action. The agency does this first in the initial statement of reasons. During the rulemaking proceeding, the agency may add new material on which it relies by notifying the public and providing a 15 day opportunity to comment on the proposal in light of the new material relied upon. The agency then states in the final statement of reasons what material has been added during the proceeding.

In addition, during the rulemaking, the public may submit recommendations or objections to the proposed regulation and submit material, including studies, reports, data, etc. for consideration by the agency and inclusion in the record. In the final statement of reasons, the agency must respond to all relevant input and explain a reason for rejecting each recommendation or objection directed at the proposed action, or explain how the proposal has been amended to accommodate the input. All of these materials constitute the record.

At the end of a rulemaking proceeding, the rulemaking agency must certify under penalty of perjury that the rulemaking record is complete and closed. The rulemaking agency then submits the complete record to OAL for review. In reviewing for compliance with the Necessity standard, OAL is limited to applicable provisions of law and the record of the rulemaking proceeding. Once OAL review is complete and the record is returned to the rulemaking agency, the file is the agency's permanent record of the rulemaking proceeding. No item in the file may be removed, altered or destroyed. Any judicial review of the regulation is based only on the evidence included in the rulemaking record.

What must be addressed in the record? Each regulation must satisfy the Necessity standard. OAL reviews the rulemaking record to ensure that each provision of regulation text that is adopted, amended, or repealed satisfies the Necessity standard.

"Necessity" means the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to facts, studies, and expert opinion. Government Code Section 11349(a).

What is "substantial evidence"? The "substantial evidence" standard used by OAL is the same as the "substantial evidence" standard used in judicial review of regulations. The following is a definition of "substantial evidence" drawn from the legislative history of the Necessity standard.

Such evidence as a reasonable person reasoning from the evidence would accept as adequate to support a conclusion.

A number of principles and limitations are involved in the application of this standard. Clearly, "substantial evidence" is more than "any evidence," but is nowhere near "proof beyond a reasonable doubt." A key characteristic of the standard is its deferential nature. The "substantial evidence" test was added to the Necessity standard by Chapter 1573, Statutes of 1982 (AB 2820). The following letter from Assemblyman Leo McCarthy to Speaker Willie Brown summarized the "substantial evidence" test as used in the Necessity standard:

"The principal addition AB 2820 makes to what we approved in AB 1111 in 1979 is a specific level of evidence that an agency must meet to demonstrate the need for a particular regulation. The standard is substantial evidence taking the record as a whole into account.

"That standard is a familiar one in the law and has been given a definite interpretation by the courts in the past. Our intent is that an agency must include in the record facts, studies or testimony that are specific, relevant, reasonable,

credible and of solid value, that together with those inferences that can rationally be drawn from such facts, studies or testimony, would lead a reasonable mind to accept as sufficient support for the conclusion that the particular regulation is necessary. Suspicion, surmises, speculation, feelings, or incredible evidence is not substantial.

"Such a standard permits necessity to be demonstrated even if another decision could also be reached. This standard does not mean that the particular regulation necessarily be 'right' or the best decision given the evidence in the record, but that it be a reasonable and rational choice. It does not mean that the only decision permitted is one that OAL or a court would make if they were making the initial decision. It does not negate the function of an agency to choose between two conflicting, supportable views.

"The proposed standard requires the assessment to determine necessity to be made taking into account the totality of the record. That means the standard is not satisfied simply by isolating those facts that support the conclusion of the agency. Whatever in the record that refutes the supporting evidence or that fairly detracts from the agency's conclusion must also be taken into account. In other words, the supporting evidence must still be substantial when viewed in light of the entire record." (California, Assembly Daily Journal, 208th Sess. 13, 663-34 (1982).)

CITATIONS

Armistead v. State Personnel Board (1978) 22 Cal.3d 198, 149 Cal.Rptr.1

Engelmann v. State Bd. of Education (1991) 2 Cal.APP.4th 47, 3 Cal.Rptr.2d 264

Grier v. Kizer (1990) 219 Cal.App.3d 422, 268 Cal.Rptr. 244

Poshman v. Dumke (1973) 31 Cal.App.3d 932, 107 Cal.Rptr. 596

Roth v. Dept. of Veteran Affairs (1980) 110 Cal.App.3d 622, 167 Cal.Rptr. 552

State Water Resources Control Board v. OAL (1993) 12 Cal.App.4th 697, 16 Cal.Rptr.2d 25

Stoneham v. Rushen (*Stoneham I*) (1982) 137 Cal.App.3d 729, 188 Cal.Rptr. 130

Yamaha v. State Board of Equalization (1998) 19 Cal.4th 1, 78 Cal.Rptr.2d

ATTACHMENT W

II. Sealed Source and Device (SS&D) Evaluation Program

31. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of devices issued during the review period. The table heading should be:

SS&D Registry Number	Distributor	Principal Use	Date Issued	Type of Action
CA1080D103S	Varian Medical Systems, Inc.	(V) General Medical Use	5/18/04	New – supersedes an NR SSD.
CA0406S173S	Isotope Products Laboratories	(X) Medical Reference Source	5/27/04	Amend – address change, activity increase.
CA0406S112S	Isotopes Products Laboratories	(D) Gamma Gauges and (U) X-Ray Fluorescence	7/12/04	Amend - supersedes CA0406S187S.
CA0406S221S	Isotopes Products Laboratories	(U) X-Ray Fluorescence	7/27/04	New.
CA0406S225S	Isotopes Products Laboratories	(X) Medical Reference Sources	8/10/04	Amend – changed maximum activity.
CA0598D115S	JL Shepherd and Associates	(K) Gamma Irradiator, Category II	8/20/04	Amend – added model for outdoor environments.
CA0380D101S	Nova R&D, Inc.	General Neutron Source Applications (H)	9/9/04	Amend – changed from GL to SL.
CA0406S121S	Isotopes Products Laboratories	(A) Industrial Radiography	9/17/04	Amend - supersedes CA0406S114U.
CA0406S116S	Isotopes Products Laboratories	(S) Foil Source	10/29/04	Amend – new source mfg. Source consolidation.
CA0102D104S	ADAC Laboratories	(Y) Calibration.	11/24/04	Amend – added a model. Updated mfg.
CA0102D105S	ADAC Laboratories	(Y) Calibrators	12/22/04	New.
CA0215D102B	SAIC	(D) Gamma gauge	12/29/04	Amend – increased max activity.
CA0406S195S	Isotope Products Laboratories	(A) Industrial Radiography and (D) Gamma Gauges	1/4/05	Amend – new mfg, isotope, activity.
CA0406S235S	Isotope Products Laboratories	(X) Medical Reference Sources	2/9/05	Amend – changed maximum activity.

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CA0406S234S	Isotope Products Laboratories	(S) Foil Sources	3/10/05	Amend – address correction, Microshield calculation.
CA1213S102S	Belden Engineering	(D) Gamma gauge	4/7/05	New.
CA1213D101B	Belden Engineering	(D) Gamma gauges	4/11/05	Amend – changed source model.
CA0406S232S	Isotope Products Laboratories	(F) Well Logging	7/14/05	Amend – removed a mfg. Updated name of mfg.
CA0406S182S	Isotope Products Laboratories	(D) Gamma Gauges and (X) Medical Reference Sources	7/21/05	Amend – any changes?
CA0406S180S	Isotope Products Laboratories	(X) Medical Reference Source	7/26/05	Amend – annular configuration.
CA0406S118S	Isotope Products Laboratories	X-Ray Fluorescence (U) and Gamma Gauges (D)	9/23/05	Amend – added R&D applications. Added mfg. Added use as gamma gauge.
CA0661S104S	Varian Medical Systems, Inc.	(V) General medical use.	10/25/05	Amend – updated address. Updated welding.
CA0215D105B	SAIC	(D) Gamma Gauge	11/2/05	Amend – changed G to B. General updates.
CA1080S104S	Varian Medical Systems, Inc.	General medical use (V)	12/9/05	Amend - new mfg/distr.
CA0510S126S	North American Scientific, Inc.	(V) General Medical Use	1/27/06	Amend – new ANSI rating.
CA0598S126S	J.L. Shepherd & Associates	(K) Gamma irrad cat II, (J) gamma gauge cat I	1/8/06	Amend – new ANSI rating.
CA1050S102S	Golden Triangle Medical Technologies, Inc.	(C) Medical teletherapy	2/15/06	Amend – new name and address.
CA1050D101S	Golden Triangle Medical Technologies, Inc.	(C) Medical teletherapy	2/14/06	Amend – new name and address.
CA0471D101B	NDC Infrared Engineering, Inc.	X-ray Fluorescence (U)	2/16/06	Amend – new name and address, added shutter, new source.
CA1046D102S	Analyser Systems, Inc.	(H) General Neutron Source Application	2/28/06	New.
CA0598S127S	JL Shepherd & Associates	(K) Gamma irrad cat II, (J) gamma	1/18/06	Amend – changed ANSI rating.

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		gauge cat I		
CA0305D113S	Thermo Electron Corporation	(H) General Neutron Source Applications	12/6/05	Amend – new address, source/ANSI rating.
CA1050S102S	American Radiosurgery, Inc.	(C) Medical teletherapy	3/23/06	Amend – new name.
CA1050D101S	American Radiosurgery, Inc.	(C) Medical teletherapy	3/24/06	Amend – new name.
CA0406S214S	Isotope Products Laboratories	(S) Foil Source	4/20/06	Amend – changed temp classification.
CA0305D111S	Thermo Electron Corporation	(U) X-Ray Fluorescence	5/3/06	New.
CA0181D101G	Beckman Coulter, Inc.	(T) Other	5/11/06	Amend – Part 21 defect.
CA0598D113S	J. L. Shepherd & Associates	Gamma Irradiator, Category I (J)	5/25/06	Amend - Added model.
CA0598D123S	J. L. Shepherd & Associates	Calibrator (Y)	5/19/06	Amend – added Am-241.
CA0406D237S	Isotope Products Laboratories	(D) Gamma Gauges	6/29/06	Amend – added indicator light.
CA0215D109B	Science Applications International Corporation, Inc.	(D) Gamma Gauge	7/11/06	Amend – Changed G to B.
CA0406D107S	Isotope Products Laboratories	(I) Calibration Sources, and (X) Medical Reference Sources	7/14/06	Amend – added isotopes.
CA0406S106S	Isotope Products Laboratories	(I) Calibration Sources, and (X) Medical Reference Sources	8/25/06	Amend – source types/isotopes.
CA0215D109B	Science Applications International Corporation, Inc.	(D) Gamma Gauge	8/29/06	Amend – changed label.
CA1259D101S	HiEnergy Technologies, Inc.	(H) General Neutron Source Applications	9/29/06	New.
CA0598S119S	J. L. Shepherd and Associates	(J) Gamma Irradiator Category I (J), Calibrator Category II (K)	9/30/06	Amend - new address.

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CA0598S122S	J. L. Shepherd and Associates	Gamma Irradiator Category I (J) or Category II (K) or Calibrators (Y)	10/31/06	Amend – added manufacturer/address.
CA0208S101S	CPN International, Inc.	(G) Portable Moisture Density Gauge	1/4/07	Amend – changed address.
CA0208D102S	CPN International, Inc.	(G) Portable Moisture Density Gauge	1/4/07	Amend – changed address.
CA0208D104S	CPN International, Inc.	(G) Portable Moisture Density Gauge	1/4/07	Amend – changed address.
CA0208D105S	CPN International, Inc.	(G) Portable Moisture Density Gauge	1/4/07	Amend – changed address.
CA0208D106S	CPN International, Inc.	(G) Portable Moisture Density Gauge	1/4/07	Amend – changed address.
CA0208D107S	CPN International, Inc.	(G) Portable Moisture Density Gauge	1/4/07	Amend – changed address.
CA0208D108S	CPN International, Inc.	(G) Portable Moisture Density Gauge	1/4/07	Amend – changed address.
CA0208D109S	CPN International, Inc.	(G) Portable Moisture Density Gauge	1/4/07	Amend – changed address.
CA1195D101S	SABIA, Inc.	(H) General Neutron Source Application	7/27/06	Amend – changed source model name.
CA0305D104S	Thermo Gamma Metrics	(H) General Neutron Source Applications	6/4/07	Amend – changed name, address.
CA0305D101S	Thermo Gamma Metrics	Other	6/7/07	Amend – changed name, address, and source.
CA0305D109S	Thermo Gamma Metrics	(H) General Neutron Source Applications	6/1/07	Amend – changed name, address, and source.
CA0510D130S	North American Scientific	Manual brachytherapy (AA)	7/2/07	New.
CA0305D105S	Thermo Gamma Metrics	(H) General Neutron Source Applications	6/27/07	Amend – changed name, address, and source.

ATTACHMENT W

CA0406S238S	Eckert & Ziegler Isotope Products	(D) Gamma Gauges and (X) Medical Reference Sources	7/11/07	New. Supersedes WA SSD.
CA8169S801S	Radiance Medical Systems, Inc.	(V) General medical use	7/11/07	CA1109S801S was inactivated.
CA0598D115S	J.L. Shepherd & Associates	(K) Gamma Irradiator, Category II	6/22/07	Amend – added model.
CA0305D102S	Thermo Gamma Metrics	(H) General Neutron Source Applications	8/14/07	Amend – changed name, address, add source.
CA0305D106S	Thermo Gamma Metrics	(H) General Neutron Source Applications	8/14/07	Amend – changed name, address, add source.
CA1218D102S	Rapiscan Systems Neutronics	(D) Gamma Gauge	2/8/07	New.
CA1046D101B	Thermo Gamma Metrics	(H) General Neutron Source Applications	10/10/07	Amend – changed name. Add source.
CA0309D103G	General Atomics	(D) Gamma Gauge	11/6/07	New.
CA0406S232S	Eckert & Ziegler Isotope Products	(F) Well Logging	11/27/07	Amend – changed pressure test.
CA0406S228S	Eckert & Ziegler Isotope Products	(A) Industrial Radiography (D) Gamma Gauges (F) Well Logging	12/5/07	Amend – added well logging source.
CA0208S101S	CPN International, Inc.	(G) Portable Moisture Density Gauge	12/19/07	Amend – changed name of manufacturer.
CA0215D102B	Science Applications International Corp	(D) Gamma Gauge	1/10/08	Amend – added gauge.
CA0305D101S	Thermo Gamma Metrics	Other	10/22/07	Amend – added source manufacturer.
CA0305D102S	Thermo Gamma Metrics	(H) General Neutron Source Applications	10/22/07	Amend – added source manufacturer.
CA0305D104S	Thermo Gamma Metrics	(H) General Neutron Source Applications	10/22/07	Amend – added source manufacturer.
CA0305D105S	Thermo Gamma Metrics	(H) General Neutron Source Applications	10/22/07	Amend – added source manufacturer.
CA0305D106S	Thermo Gamma	(H) General	10/22/07	Amend – added source

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	Metrics	Neutron Source Applications		manufacturer.
CA0305D109S	Thermo Gamma Metrics	(H) General Neutron Source Applications	10/22/07	Amend – added source manufacturer.
CA0305D113S	Thermo Gamma Metrics	(H) General Neutron Source Applications	10/22/07	Amend – added source manufacturer.
CA0406S195S	Eckert & Ziegler Isotope Products	(A) Industrial Radiography, (D) Gamma Gauges, (F) Well Logging	1/23/08	Amend – added well logging source.
CA0406S184S	Eckert & Ziegler Isotope Products	(T) Other, (X) Medical Reference Sources	1/14/08	Amend – added Co-57.
CA0406S214S	Eckert & Ziegler Isotope Products	(S) Foil Source	1/31/08	Amend – updated source geometry/leak testing.
CA661D103S	Varian Medical Systems, Inc.	Photon-emitting remote afterloaders (AC)	1/30/08	Amend – Part 21. Also, add model.

32. Please include information on the following questions in Section A, as they apply to the SS&D Program:

Technical Staffing and Training - Questions 2-9

2. Please provide the following organization charts, including names and positions:

   (a) A chart showing positions from Governor down to Radiation Control Program Director;

   (b) A chart showing positions of current radiation control program including management; and

   (c) Equivalent charts for sealed source and device evaluation, low-level radioactive waste and uranium recovery programs, if applicable.

3. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) full-time equivalents (FTE) applied to the radioactive materials program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas:

administration, materials licensing & compliance, emergency response, low-level radioactive waste, uranium recovery, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

Name	Position	Area of Effort	FTE%

4. Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, as appropriate.

5. Please list all professional staff who have not yet met the qualification requirements for a license reviewer or materials inspector. For each, list the courses or equivalent training/experience they need and a tentative schedule for completion of these requirements.

6. Identify any changes to your qualification and training procedure that occurred during the review period.

7. Please identify the technical staff that left your program during the review period.

8. List any vacant positions in your program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

9. For Agreement States, does your program have an oversight board or committee which provides direction to the program and is composed of licensees and/or members of the public? If so, please describe the procedures used to avoid any potential conflict of interest.

Technical Quality of Licensing Actions - Questions 18-23

18. How many specific radioactive material licenses does the Program regulate at this time?

19. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period.

20. Identify any licensees or groups of licensees that were issued increased controls during the review period. Those licensees that were initially identified during the initial implementation of increased controls need not be listed.

21. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

22. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

23. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

Technical Quality of Incident and Allegation Activities - Questions 24-26

24. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See Procedure SA-300, *Reporting Material Events*, for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:

Licensee Name	License #	Date of Incident/Report	Type of Incident

25. During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified? For States, was timely notification made to NRC? For Regions, was an appropriate and timely PN generated? For Agreement States, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.

26. Identify any changes to your procedures for responding to incidents and allegations that occurred during the period of this review.